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UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

WESTERN DIVISION

UNITED STATES OF AMERICA, the STATES OF ALASKA, CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VERMONT, VIRGINIA, and WASHINGTON, and the DISTRICT OF COLUMBIA *ex rel.* NICHOLAS FINCH and NICHOLAS SACCOMANNO,

Plaintiffs/Relators,

vs.

NIHON KOHDEN CORPORATION; NIHON KOHDEN AMERICA, INC.; NIHON KOHDEN ORANGEMED, INC.; and NKUS LAB.

Defendants.

No. CV 18-06352-ODW (MAAx)

AMENDED COMPLAINT FOR VIOLATIONS OF THE FEDERAL AND STATE FALSE CLAIMS ACTS; DEMAND FOR JURY TRIAL

[FILED UNDER SEAL PURSUANT TO THE FALSE CLAIMS ACT, 31 U.S.C. §§ 3730(b)(2) and (3)]

DO NOT ENTER ON PACER

Relators Nicholas Finch ("Mr. Finch") and Nicholas Saccomanno ("Mr. Saccomanno") (collectively, the "Relators"), by and through the undersigned counsel, and on behalf of the United States of America ("United States") and the States of Alaska, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Vermont, Virginia, State of Washington, and the District of Columbia (collectively, the "States"), hereby allege as follows:

I. INTRODUCTION

1. This is a *qui tam* action by Relators, filed on behalf of the United States and States, against Nihon Kohden Corporation ("NK Corporation"), Nihon Kohden America, Inc. ("NK America") Nihon Kohden OrangeMed, Inc. ("NK OrangeMed"), and NKUS Lab (collectively, "Nihon Kohden" or "Defendants") for using, making, presenting, and causing to make, use, or present false statements and claims to the governments of the United States and States (collectively, the "Government") in violation of the False Claims Act, 31 U.S.C. § 3729, *et seq.* and applicable State law.

2. This case is about the fraudulent practices occurring at Nihon Kohden—an international giant in the medical device industry earning hundreds of millions in global revenue each year. In 2017 alone, Nihon Kohden generated $18.9 billion yen (approximately $170 million USD) in medical device sales in just the Americas—primarily in the United States.[1] In addition, in 2016, NK America was also awarded a $35 million federal contract with the U.S. Department of Defense for patient monitoring

[1] This figure is from Nihon Kohden's 2017 annual report which is consolidated for NK Corporation and its subsidiaries, including NK America. *Nihon Kohden Report* 2017 at 18, https://www.nihonkohden.com/ir/library/pdf/NKreport2017E.pdf (last visited July 3, 2018).

equipment.[2]

3. The fraud alleged herein is straightforward. Since at least 2012—but upon information and belief, as early as 2008—Nihon Kohden has unlawfully marketed, distributed and sold various adulterated/misbranded/off-label patient monitoring medical devices without the necessary premarket government approval. More specifically, Nihon Kohden has a corporate-wide practice and culture of entirely ignoring the Food and Drug Administration ("FDA")'s 510(k) clearance process. And since the arrival of NK America's current CEO in 2014, Dr. Wilson Constantine, this fraud has continued to worsen and grow each year.[3]

4. This fraud involves multiple patient monitoring devices, including, but not limited to, Nihon Kohden's: (i) BSM-1700 monitor(s); (ii) BSM-3500 monitor(s); (iii) tele-transmitter(s); (iv) remote network station(s) ("RNS(s)"); (v) central nurse station(s) ("CNS(s)"); (vi) Life Scope G9 monitor(s); (vii) NetKonnect remote monitor(s); and (viii) the ViTrac mobile application (all adulterated/misbranded/off-label products together, the "Monitoring Devices"). All of these Monitoring Devices are adulterated/misbranded/off-label and have been adulterated/misbranded/off-label for a number of years, but were nonetheless marketed, distributed and sold by Nihon Kohden. Relators believe that ***over***

[2] Contract No. SPM2D1-12-D-8300 is a one-year base contract with eight one-year option periods for patient monitoring equipment, to be used by the Air Force, Army, Navy, Marine Corps, and federal civilian agencies. *Contracts: Defense Logistics Agency*, U.S. DEP'T OF DEFENSE (Oct. 26, 2016), *available at https://www.defense.gov/News/Contracts/Contract-View/Article/987608/* (last visited July 5, 2018).

[3] The current CEO of NK America—Dr. Wilson P. Constantine—was previously a vice president of OtisMed Corporation and Stryker Corporation in 2014, when OtisMed pleaded guilty and paid over $80 million to resolve allegations that it violated FDA marketing clearance regulations and introducing adulterated medical devices into interstate commerce. *OtisMed Corporation and Former CEO Plead Guilty to Distributing FDA-Rejected Cutting Guides for Knee Replacement Surgeries: Corporation to Pay More than $80 Million to Resolve Criminal and Civil Investigations*, U.S. DEP'T OF JUSTICE, U.S. Attorney's Office District of New Jersey (Dec. 8, 2014), *available at* https://www.justice.gov/usao-nj/pr/otismed-corporation-and-former-ceo-plead-guilty-distributing-fda-rejected-cutting-guides (last visited July 3, 2018).

50% of all of Nihon Kohden's devices are adulterated/misbranded/off-label, and that ***the particular devices discussed herein make up well over half of Nihon Kohden's annual revenue in the U.S.***

5. Rather than go through the proper FDA channels, Nihon Kohden side-steps the 510(k) clearance process altogether by simply adding an internal "letter to the file" ("LTF") to a different device that received 510(k) clearance years earlier. These internal LTFs are improper because the Monitoring Devices are significantly different from any previously-cleared devices and, therefore, require their own independent 510(k) clearance. For years, Nihon Kohden has purposely evaded this requirement in order to rush its adulterated/misbranded/off-label Monitoring Devices to market without being delayed by the FDA clearance process. Simply put, market demand and profits have superseded regulatory requirements for a number of years

6. Over the years, multiple employees, including Relators, have voiced concerns to corporate leadership about the internal LTF process and the adulterated/misbranded/off-label devices. To date, Nihon Kohden has purposely ignored and rebuked all such complaints. As a result, the fraud still continues to this day.

7. In addition, Nihon Kohden has received multiple complaints from consumers regarding these Monitoring Devices. But because these devices are all adulterated/ misbranded/off-label, Nihon Kohden never submitted any of these complaints to the FDA. Had it done so, it would have notified the FDA that it was marketing and distributing adulterated/misbranded/off-label devices—thereby blowing the whistle on itself. As a result, numerous consumer complaints go unreported each year. In fact, Nihon Kohden has even recalled several Monitoring Devices in response to consumer complaints. But once again, because these Monitoring Devices are all adulterated/misbranded/off-label and not filed with the FDA, these recalls go unreported as well.

8. As further evidence of this corporate-wide fraud, Nihon Kohden has gone through 4–5 Directors of Quality Assurance in the past 5 years. Upon information and belief, the current Director of Quality Assurance resigned in October 2018 after raising

concerns over the several thousands of product complaints that have gone unreported to the FDA and about Nihon Kohden's non-compliance with the 510(k) process. Upon further information and belief, the Director stated that she "***was not going to jail for this company***."

9. Under the terms of the False Claims Act, this Amended Complaint is to be filed *in camera* and under seal and is to remain under seal for a period of at least 60 days and shall not be served on Defendants until the Court so orders. The Government may elect to intervene and proceed with the action within the 60-day time frame, or within any extensions of that initial sixty-day period granted by the Court for good cause shown, after it receives both the Amended Complaint and the statement of material evidence submitted to it.

II. NATURE OF THE ACTION

10. This is an action to recover treble damages and civil penalties arising from the fraudulent conduct of Defendants for using, making, presenting, and causing to make, use, or present false statements and claims to the Government in violation of the False Claims Act, 31 U.S.C. § 3729 *et seq*. and all applicable State laws (collectively, the "False Claims Act").

11. Under the False Claims Act, a private person may bring an action in federal district court for himself and for the United States and States, and may share in any recovery. 31 U.S.C. § 3730(b). That private person is known as a "Relator" and the action that the Relator brings is called a *qui tam* action.

III. JURISDICTION AND VENUE

12. This Court has subject matter jurisdiction to adjudicate this action under 28 U.S.C. §§ 1331 and 1345.

13. This Court has personal jurisdiction over the Defendants pursuant to 31 U.S.C. § 3732(a) because Defendants transact and have transacted business in this District.

14. Venue is proper in this District under 31 U.S.C. § 3732 and 28 U.S.C. § 1391(b) and (c) because Defendants are located in and transact business in this District.

IV. THE PARTIES

15. The Relators bring this action on behalf of the United States, including its agency, the Department of Health and Human Services ("HHS"), its component, the Centers for Medicare & Medicaid Services ("CMS," formerly the Health Care Financing Administration ("HCFA")), and all other Government healthcare programs, such as Medicaid, TRICARE/CHAMPUS, Blue Cross/Blue Shield – CHIP, and Veterans Administration ("VA").

16. The Relators also bring this action on behalf of all other United States agencies and departments, including the Department of Defense, the United States Army, the United States Air Force, the United States Navy, the United States Marine Corps., and all related agencies thereto.

17. The Relators also bring this action on behalf of the States of Alaska California, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Vermont, Virginia, Washington, and the District of Columbia, along with all state counterpart agencies to the federal agencies referenced above.

18. The Relators also bring this action on behalf of themselves, as permitted under the False Claims Act.

a. Relator Nicholas Finch is a citizen of the United States and a resident of the State of Washington who has spent the last six years in the patient monitoring industry. From 2013 to 2018, Mr. Finch worked at NK America as a Level 2 Project Manager where he was responsible for managing and developing for market release new product interfaces for Nihon Kohden's patient monitoring devices. Mr. Finch resigned from NK America in June 2018 due to the 510(k) issues regarding the adulterated/misbranded/off-label products alleged herein.

b. Relator Nicholas Saccomanno is a citizen of the United States and a

resident of the State of California with 8 years at years of industry experience. Mr. Saccomanno worked at NK America as a Project Manager (from 2010 to 2013) and Senior Project Manager (from 2015 to 2018) where he led project development for patient monitoring devices for market release. Mr. Saccomanno resigned from NK America in April 2018 due to the 510(k) issues regarding the adulterated/misbranded/off-label products alleged herein.

19. Mr. Finch and Mr. Saccomanno both discovered the allegations set forth herein while employed at NK America. Relators are original sources of these allegations, and have direct and independent knowledge of the information on which the allegations set forth in this Amended Complaint are based.

20. Defendant Nihon Kohden Corporation is a Japanese corporation with its principal place of business at 1-13-4 Nishiochiai, Shinjuku-ku, Tokyo 161-8560, Japan. NK Corporation is a global manufacturer, developer, and distributor of medical electronic equipment, including electroencephalograms (EEGs), electromyography (EMG) measuring systems, electrocardiograms (ECGs or EKGs) and other patient monitors.

21. Defendant Nihon Kohden America, Inc. is a California corporation with its principal place of business located at 15353 Barranca Parkway, Irvine, California 92618. NK America is a subsidiary of NK Corporation. NK America develops, manufacturers, and distributes Nihon Kohden medical electronic equipment for patient monitoring throughout the North American region.

22. Defendant Nihon Kohden OrangeMed, Inc. is a California corporation with its principal place of business located at 1800 E. Wilshire Avenue, Santa Ana, California 92705. NK OrangeMed is a sales and research/development subsidiary of NK Corporation. NK OrangeMed researches and develops devices that use Nihon Kohden's hardware and software technologies, including its patient monitoring systems. *About Kohden OrangeMed*, Nihon Kohden OrangeMed Inc., *available at* http://www.orange-med.com/.

23. Defendant NKUS Lab is a California corporation with its principal place of business located at 14 Bunsen, Irvine, California 92618. NKUS Lab is a research/development and product development subsidiary of NK Corporation. NKUS Lab creates software and hardware solutions that are incorporating into Nihon Kohden's various products, including its patient monitoring products. *Welcome to NKUS Lab*, Nihon Kohden, *available at* http://www.nklab.com/.

V. LEGAL FRAMEWORK

A. The False Claims Act

24. The False Claims Act ("FCA") imposes civil liability upon any person who:

> (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; [or]
>
> . . . .
>
> (G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government.

31 U.S.C. § 3729(a). The Affordable Care Act requires a person who has received an overpayment from the Government to report and return the overpayment within 60 days of identification, or the date that any corresponding cost report is due; and failure to report and return the overpayment is an obligation for purposes of the False Claims Act under 31 U.S.C. § 3729(a)(1)(G). *See* 42 U.S.C. § 1320a-7k(d).

25. For purposes of the FCA, the terms "knowing" and "knowingly":

> (A) mean that a person, with respect to information – (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information; and
>
> (B) require no proof of specific intent to defraud.

31 U.S.C. § 3729(b). Effective November 2, 2015 (the date of enactment of the Federal Civil Penalties Inflation Adjustment Act, Improvements Act of 2015, Public Law 114-74,

sec. 701 ("2015 Amendments")), the penalties increased from a minimum-maximum per-claim penalty of $5,500 and $11,000 to $10,781 and $21,563. The increased amounts apply to civil penalties assessed for violations occurring after November 2, 2015. Violations that occurred on or before November 2, 2015 are subject to the previous penalty amounts. On February 3, 2016, pursuant to the 2015 Amendments annual re-indexing of the FCA penalties for inflation, the civil penalties again increased to a minimum-maximum per-claim penalty of $10,957 and $21,916. As of January 19, 2018, the FCA penalties were again increased to the current minimum-maximum per-claim penalty of $11,181 and $22,363.

B. The Medicare Program

26. The Health Insurance for the Aged and Disabled Program, popularly known as the Medicare program, was created in 1965 as part of the Social Security Act ("SSA") to pay the costs of certain healthcare services for eligible individuals. The Secretary of Health and Human Services ("HHS"), an agency of the United States whose activities, operations, and contracts are paid from federal funds, administers the Medicare program through the Centers for Medicare and Medicaid Services ("CMS"), a component of HHS.

27. Medicare is a 100% federally subsidized health insurance system for eligible Americans, including those aged 65 and older, certain disabled people, and certain people with chronic diseases who elect coverage. 42 U.S.C. § 1395c; *see* 42 U.S.C. §§ 1395j-1395w. To participate in Medicare, a provider must sign and file a Provider Agreement with CMS promising compliance with applicable statutes, regulations, and guidance. 42 U.S.C. § 1395cc; 42 C.F.R. § 412.23(e)(1). Medicare service providers have a legal duty to familiarize themselves with Medicare's reimbursement rules, including those delineated in the Medicare Manuals. *Heckler v. Cmty. Health Serv. of Crawford Co., Inc.,* 467 U.S. 51, 64–65 (1984).

28. Under Medicare Part B, providers are typically compensated for the services they provide to Medicare beneficiaries on a "fee-for-service" basis as determined by Medicare's fee schedule. 42 U.S.C. § 1395w-4. To obtain compensation, providers must

deliver a compensable service, certify that the service was medically necessary for the health of the patient, certify that the service was personally furnished by the physician (or under his or her immediate supervision), and determine the appropriate diagnosis and procedure code to describe the problem and service for billing.

29. In order to bill Medicare, a provider must submit a form called the CMS 1500. The form describes, among other things, the provider, the patient, the referring physician, the services provided by procedure code, the related diagnosis code(s), the dates of service, and the amounts charged. The provider certifies on the CMS 1500 claim that the information provided is truthful and that the services billed on the form were "medically indicated and necessary."

30. Reimbursement for Medicare claims is made by the United States through HHS. CMS is an agency of HHS and is directly responsible for the administration of the Medicare program. CMS, in turn, contracts with private insurance carriers to administer and pay claims from the Medicare Trust Fund. *See* 42 U.S.C. § 1395u. Claims submitted for reimbursement are to be paid in accordance with the Social Security Act, Code of Federal Regulations, and Medicare Rules and Regulations promulgated by CMS.

C. <u>The Medicaid Program</u>

31. Medicaid is a joint federal-state program that pays for healthcare services for low-income individuals, including pregnant women, children, and parents and other caretaker relatives, as well as elderly and disabled individuals. As a result of the Affordable Care Act, each state had the option to expand eligibility for Medicaid beginning in calendar year 2014 to all nonelderly adults with income below 138 percent of the federal poverty guidelines.

32. Medicaid is jointly funded by state and federal governments. The federal government's share of each state's Medicaid spending, known as the Federal Medical Assistance Percentage ("FMAP"), is based upon the state's per capita income compared to the national average. 42 U.S.C. § 1396d(b). Such share must be at least 50 percent, but no more than 83 percent, and historically has averaged about 57 percent. In other words,

the federal government guarantees to match at least $1 in federal funds for every $1 any individual state spends on its Medicaid program.

33. State Medicaid programs must comply with the minimum requirements set forth in the federal Medicaid statute to qualify for federal funding. 42 U.S.C. § 1396a. In order to receive reimbursement from Medicaid, a provider must submit a signed claims form to the state's Medicaid program, certifying that the information on the form is "true, accurate, and complete." 42 C.F.R. § 455.18. The provider further certifies that it "understand[s] that payment of this claim will be from federal and state funds, and that any falsification, or concealment of a material fact, may be prosecuted under federal and state laws." *Id*.

D. Regulation of Medical Devices

34. The Food & Drug Administration ("FDA") is a federal governmental agency responsible for protecting the health and safety of the public by assuring, among other things, that medical devices are safe and effective for their intended uses and that the labeling of such devices bear true and accurate information. Under the federal Food, Drug and Cosmetic Act (21 U.S.C. §§ 301–397, the "FDCA"), the FDA regulates the manufacture, labeling, and shipment in interstate commerce of such devices.

35. Under the FDCA, every manufacturer of a device is required to obtain authorization from the FDA prior to marketing its devices, unless the device is a Class I or II device and the manufacturer can demonstrate that the device is "substantially equivalent" to another device already legally marketed in the United States.

36. To establish "substantial equivalence," the manufacturer must submit a Section 510(k) application to the FDA which establishes that the new device: (1) has the same intended use as a predicate device; and (2) the device either (a) has the same technological characteristics as the predicate, or (b) does not raise new questions of safety or efficacy and demonstrates that the new device is at least as safe and effective as the old device. In order obtain Section 510(k) clearance, the device must have the same intended use as an existing, legally marketed device.

37. To be eligible for Medicare/Medicaid coverage, a product or device must be "reasonable and necessary" for the treatment of illness or injury or to improve functioning of a malformed body member. CMS has interpreted this "reasonable and necessary" standard to require that a product or device—at minimum—be safe and effective, which in turn, means that, unless exempt, it must have been approved or cleared for marketing by the FDA. Medical devices that lack approval from the FDA are not reimbursable. 42 C.F.R. § 411.15(o) and 405.211(c).

38. Federal regulations also provide that a manufacturer must submit a premarket notification submission, such as a 510(k) request, when "[t]he device is one that the person currently has in commercial distribution . . . but ***that is about to be significantly changed or modified in design, components, method of manufacture, or intended use.***" 21 C.F.R. § 807.81 (emphasis added).

39. A device is "adulterated" if it is required to have, but does not have, FDA premarket approval for its intended use. The FDCA prohibits the introduction of adulterated medical devices into interstate commerce. 21 U.S.C. § 331(a).

40. A device is "misbranded" if the manufacturer of that device was required to file a 510(k) premarket notification with the FDA 90 days prior to introducing the device into interstate commerce and failed to do so. The FDCA prohibits the introduction of misbranded medical devices into interstate commerce. 21 U.S.C. § 331(a).

41. Adulterated devices and misbranded devices may not be introduced into commerce, and neither are eligible for use or reimbursement by Medicare, Medicaid, or any other health insurance program funded by the Government.

VI. FACTUAL ALLEGATIONS

42. Since at least 2012—but upon information and belief, as early as 2008—Nihon Kohden has unlawfully marketed, distributed and sold various adulterated/misbranded/off-label patient monitoring medical devices without the necessary premarket government approval. More specifically, Nihon Kohden has a corporate-wide practice and culture of entirely ignoring the FDA's 510(k) clearance

process.

43. Rather than go through the proper FDA channels, Nihon Kohden side-steps the 510(k) clearance process altogether by simply adding an internal "letter to the file" to another device that received 510(k) clearance years earlier. These internal LTFs are improper because the Monitoring Devices are significantly different from any previously-cleared devices and, therefore, require their own independent 510(k) clearance. For years, Nihon Kohden has purposely evaded this requirement in order to rush its Monitoring Devices to market without being delayed by the FDA clearance process. Simply put, market demand and profits have superseded regulatory requirements for a number of years.

44. By way of example, some of Nihon Kohden's most adulterated and misbranded devices include, but are not limited to: its: (i) BSM-1700 monitor(s); (ii) BSM-3500 monitor(s); (iii) tele-transmitter(s); (iv) remote network station(s) ("RNS(s)"); (v) central nurse station(s) ("CNS(s)"); (vi) Life Scope G9 monitor(s); (vii) NetKonnect remote monitor(s); and (viii) the ViTrac mobile application. For a quick general overview, a specification sheet describing many of these devices' characteristics is attached hereto as **Exhibit A**.

45. These devices are further discussed below:

A. The BSM-1700 Bedside Monitor

46. Back in 2008, Nihon Kohden received 510(k) clearance for its BSM-6000 series bedside monitor on the basis that it was substantially equivalent to certain other Nihon Kohden predicate devices—namely, the BSM-5130A and the ORG-9700. A true and accurate copies of Nihon Kohden's marketing brochure for the BSM-6000 series bedside monitor and its specification sheet are attached hereto as **Exhibit B** and **Exhibit C**, respectively.

47. In 2011, Nihon Kohden introduced the BSM-1700. It is considered the world's smallest fully-featured patient monitor, and is one of Nihon Kohden's best-selling devices. A true and accurate copy of Nihon Kohden's marketing brochure for the BSM-

1700 is attached hereto as **Exhibit D**.

48. The BSM-1700 is a bedside monitor capable of serving as a WLAN transport monitor, standard transport monitor, stand-alone monitor, or an input unit for the BSM-6000 bedside monitor. When not being used as a stand-alone model or transport monitor, the BSM-1700 serves a host device to the BSM-6000 series. The BSM-1700 displays the patient's parameters on a screen, communicates the patient's data over a network, and charges the internal batteries of the BSM-1700. When the patient is transferred to a different location, the BSM-1700 disconnects from the 6000 series (which remains stationary) and goes with the patient to his or her next location. The BSM-1700 is considered the world's smallest fully featured transport monitor; and compared to the BSM-6000 series, had significant changes and modifications to its design, material, energy source, manufacturing process, and its intended use.

49. A comparative review of the BSM-1700 versus the BSM-6000 further illustrates the differences between these two monitoring devices. Such differences include, but are not limited to, differences in size, weight, resolution, power source, multi-functionality, user interface operations, internal software, and device hardware. A true and accurate copy of Nihon Kohden's "Bedside Monitor Specification Comparison," which outlines the differences between the BSM-1700 and BSM-6000, is attached hereto as **Exhibit E**.

50. Given these significant changes and modifications, Nihon Kohden was required to file a premarket notification submission with the FDA seeking independent 510(k) clearance for the BSM-1700 device. Nihon Kohden was required to demonstrate how—despite these significant changes—the BSM-1700 was still substantially equivalent to the BSM-6000 series. To date, Nihon Kohden has failed to file any such submission. Instead, it simply filed an internal LTF against its original BSM-6000 series, and introduced the BSM-1700 into commerce without any premarket clearance/approval.

51. Since the BSM-1700 was first introduced in 2011, the device has undergone additional software and hardware changes, each of which have been documented by

additional internal LTFs against the original 6000 series. There are now nearly a dozen internal LTFs for the various changes made to the BSM-1700—all of which were applied against the original BSM-6000 series. Once again, the BSM-1700 to this day still has no independent clearance on its own.

52. Nihon Kohden knew that a new 510(k) submission was required for the BSM-1700, yet intentionally chose not to file one. For example, an internal email amongst Nihon Kohden personnel and leadership dated December 9, 2014, subject line titled "RE: Software upgrade: BWM-1700 VO1-10" states:

> With these changes I am in agreement that the LTF is appropriate. ***I remain concerned however that this device needs a catch-up 510(k)*** as the original introduction of the device raises questions that we would find difficult to defend. ***The more changes we make to the device the more difficult it will be to indicate why the device does not have an independent clearance.***

Nihon Kohden's CEO, Dr. Wilson Constantine, was copied on this email.

53. The BSM-1700 has now been on the market for several years and is used regularly by hospitals and healthcare providers throughout the United States. The BSM-1700 costs approximately $7,560.00 to $7,830.00. This is Nihon Kohden's highest selling device and is one of its greatest revenue generators.

B. <u>The BSM-3500 Bedside Monitor Series</u>

54. In 2014, Nihon Kohden introduced the BSM-3500—another bedside monitor that, like the BSM-1700, has an internal LTF filed against the BSM-6000 and lacks its own FDA clearance or approval. The BSM-35000 is an all-in-one bedside monitor specifically designed for ambulatory and specialty center use. A true and accurate copy of Nihon Kohden's marketing brochure for the BSM-3500 is attached hereto as **<u>Exhibit F</u>**.

55. Compared to the BMS-6000 series, the BSM-3500 had significant changes and modifications to its design, material, energy source, manufacturing process, and its intended use. A true and accurate copy of Nihon Kohden's "Bedside Monitor Specification Comparison," which outlines the differences between the BSM-3500 and the BSM-6000, is attached hereto as **<u>Exhibit E</u>**.

56. As a result, Nihon Kohden was required to file a premarket notification submission with the FDA seeking independent 510(k) clearance for the BSM-3500 device. Nihon Kohden was required to demonstrate how—despite these significant changes—the BSM-3500 was still substantially equivalent to the BSM-6000 series.

57. To date, Nihon Kohden has failed to file any such submission—and the BSM-3500 has no FDA approval or clearance. Instead (and as with the BSM-1700), Nihon Kohden simply filed an internal LTF against its original BSM-6000 series, and introduced the BSM-3500 into commerce without any premarket clearance/approval. In a letter to the FDA dated August 25, 2015, Nihon Kohden represented to the FDA that "[t]he BSM-3500 Series models are just additional models of the BSM-6000 Series." This statement is flat wrong.

58. Nihon Kohden continues to make additional changes to BSM-3500; and with each change, adds another internal LTF to the 6000 series. One LTF is specific to the marketing and release of the BSM-3500, describing it as an equivalent to the BSM-6000 series. Future LTFs for software changes and hardware configurations have all been filed against the original 510(k) for the BSM-6000 series (with some software/hardware changes not being LTF'd at all).

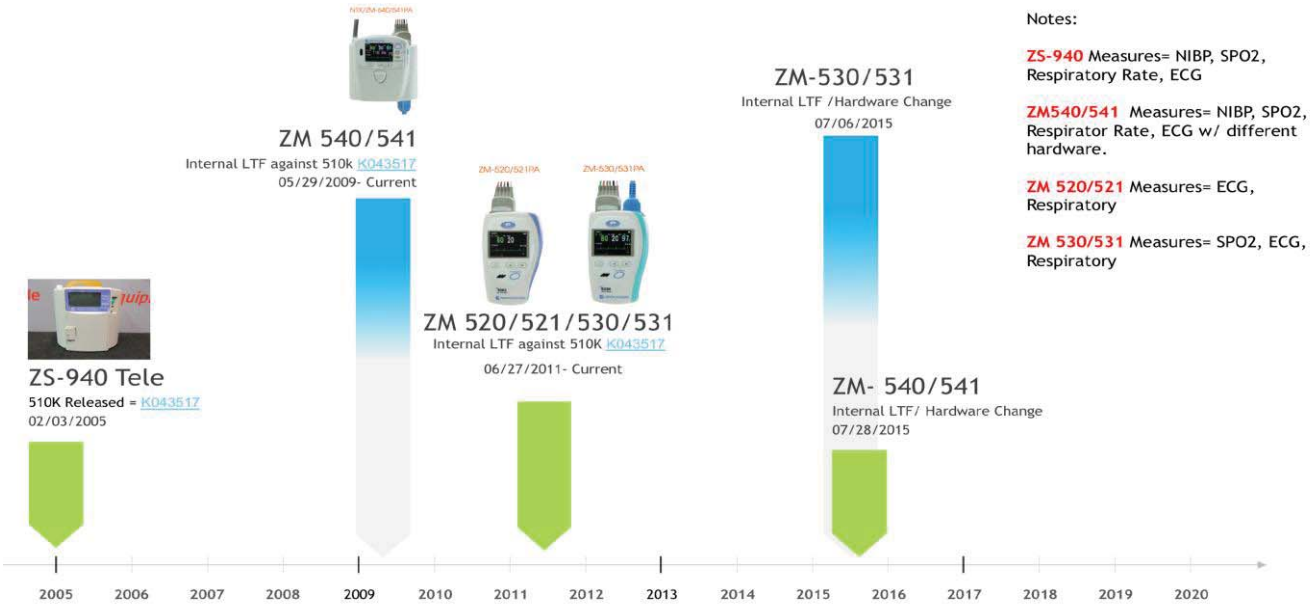
59. Like the BSM-1700, the BSM-3500 has been on the market for several years and is now regularly used by healthcare providers across the nation. The BSM-3500 is one of Nihon Kohden's top selling devices and costs approximately $6,000.

C. Tele-Transmitter(s)

60. In 2005, Nihon Kohden's ZS-940 transmitter received 510(k) clearance. Since then, Nihon Kohden has released at least ten new devices, each containing substantial changes regarding their hardware, software, user interface, and intended uses. Such devices included: (i) the ZM-540 and ZM-541 (released in 2009); (ii) the ZM-520, ZM 521, ZM-530, and ZM-531 (released in 2011), and ZM-530, ZM-531, ZM-540, and ZM-541 (released in 2015). A true and accurate copy of Nihon Kohden's marketing brochure for its tele-transmitter devices is attached hereto as **Exhibit G**.

61. These new devices are completely different compared to the original ZS-940. As such, each of these new devices required their own separate 510(k) clearance. But instead, Nihon Kohden simply added an internal LTF against its original ZS-940 device (which received clearance back in 2005). None of the new devices were submitted or reviewed by the FDA, but were nevertheless introduced marketed, distributed and sold by Nihon Kohden.

62. The following chart illustrates this timeline:



63. These tele-transmitter devices cost approximately $3,000 per transmitter, depending on the model and feature set. However, telemetry transmitters also require a receiver device which cost another $12,000 - $14,000 per device. Telemetry transmitters are some of the most popular devices sold, exceeding the volume of bedside monitor sales. These devices make up a substantial portion of Nihon Kohden's annual revenue.

D. <u>The Remote Network Station (RNS-9703)</u>

64. In 2010, Nihon Kohden obtained 510(k) clearance for its CNS-6200/6201 Central Nurse Station. The devices were cleared for use to provide cardiac and vital signs monitoring for multiple patients within a medical facility. The CNS-6200/6201 displays and records physiological data from individual bedside monitors and/or telemetry received

transmitters and mimics an alarm when a measured parameter falls outside a preset limit. A true and accurate copy of Nihon Kohden's marketing brochure for its CNS-6201 is attached hereto as **Exhibit H**.

65. In 2014, Nihon Kohden introduced the remote network station, RNS-9703, which provides for secondary monitoring of up to sixteen patients who are centrally monitored on a CNS. A true and accurate copy of Nihon Kohden's marketing brochure for its RNS-9703 is attached hereto as **Exhibit I**.

66. Compared to the CNS, the RNS has significant changes and modifications to its design, material, energy source, manufacturing process, and its intended use. For example, the CNS serves as the primary monitoring station for all BSM-6000s/1700s/3000s and tele-transmitters, allowing hospitals' nurses to view and monitor patients remotely (typically from a nurse station), and stores patient data on a hard drive. In contrast, the RNS is an independent viewing station with different hardware and software and which requires an "RNS Server" on the network to enable the devices overall functionally. Unlike the CNS, no data is stored on the RNS, and such data is displayed in real-time.

67. Given these significant changes and modifications, Nihon Kohden was required to file a premarket notification submission with the FDA seeking independent 510(k) clearance for the RNS. Nihon Kohden was required to demonstrate how—despite these significant changes—the RNS was still substantially equivalent to the CNS. To date, Nihon Kohden has failed to file any such submission. Instead, Nihon Kohden introduced the RNS-9703 as an "accessory" to the CNS as a means to circumvent the 510(k) approval process. Rather than submit a 510(k) for the RNS, Nihon Kohden simply added an internal LTF to its CNS file, and introduced the BSM-1700 into commerce without any premarket clearance/approval.

68. The RNS has now been on the market for eight years and costs approximately $7,350. Approximately 200 – 250 RNS units are sold annually.

E. The Central Nurse Stations (CNS-6200/6201)

69. As stated in Section VI.D *supra*, Nihon Kohden obtained 510(k) clearance for the CNS-6200/6201 Central Nurse Station devices in 2010. These devices were cleared for use to provide cardiac and vital signs monitoring for multiple patients within a medical facility. The devices display and record physiological data from individual bedside monitors and/or telemetry received transmitters and mimics an alarm when a measured parameter falls outside a preset limit. *See* **Exhibit H.** The predicate device was the CNS-9701, which received 510(k) clearance in 2002.

70. Since 2010, the CNS-6200/6201 devices have undergone significant software, design, and functionality changes. In their current form, the CNS-6200/6201 devices are entirely different products than the devices that received 510(k) clearance in 2010. In fact, due to the significant changes, the CNS-6200/6201 devices have suffered from numerous defects and malfunctions, causing customer complaints and (in some cases) product recalls.

71. Due to these significant changes and modifications, Nihon Kohden was required to file a premarket notification submission with the FDA seeking an updated, "catch-up" 510(k) clearance for these altered devices. But instead, Nihon Kohden simply added an internal LTF for all of these changes. None of these changes were submitted or reviewed by the FDA, yet Nihon Kohden nevertheless introduced marketed, distributed and sold the adulterated/misbranded devices. To this day, Nihon Kohden is still marketing and selling these devices without an updated, catch-up 510(k) clearance.

72. In addition, Nihon Kohden has manufactured and released entirely new CNS devices that have no 510(k) clearance at all. For example, in 2018, Nihon Kohden released the CNS-6801 device. Nihon Kohden describes the devices as "the successor of the CNS-6201A Central Station and offers the robust features of this product plus additional improvements." The differences include: (i) different operating system; (ii) different dimensions and weight; (iii) different processor; (iv) different memory; (v) different display; and (vi) different graphic user interface support. The CNS-6801 device does not

have its own, independent 510(k).

73. The CNS-6200/6201 devices have been on the market for eight years and costs approximately $40,000 and an estimated 200 – 250 units are sold annually.

F. The Life Scope G9 Bedside Monitor (CSM-1901)

74. Nihon Kohden describes its Life Scope G9 Bedside Monitor (a/k/a the CSM-1901) as a "full-featured system" that "provides comprehensive parameter monitoring with data storage, including multi-wave-form/multi-parameter full disclosure, comprehensive arrhythmia and ST segment analysis." Nihon Kohden, Life Scope G9 Bedside Monitor, *available at* https://us.nihonkohden.com/products/life-scope-g9-bedside-monitor/. A true and accurate copy of Nihon Kohden's marketing brochure for the G9 Bedside Monitor is attached hereto as **Exhibit J**.

75. The G9 Bedside Monitor received 510(k) clearance back in 2015. Since then, it has undergone substantial changes regarding its hardware, software, user interface, and intended use. Such changes, include, but are not limited to, unilaterally adding accessories to the G9 Bedside Monitor, removing the display speaker detection/notification function, continuously changing and upgrading the device's software, and revising the device's operating manual.

76. Given these significant changes and modifications, Nihon Kohden was required to file a premarket notification submission with the FDA seeking an updated, "catch-up" 510(k) clearance for the G9 Bedside Monitor. But instead, Nihon Kohden simply added an internal LTF for all of these changes. None of these changes were submitted or reviewed by the FDA, yet Nihon Kohden nevertheless introduced marketed, distributed and sold the adulterated/misbranded G9 Bedside Monitor. To this day, Nihon Kohden is still marketing and selling the G9 Bedside Monitor without an updated, catch-up 510(k) clearance.

77. The G9 Bedside Monitor has been on the market for over three years and costs approximately $20,000 and an estimated 250 – 350 units are sold annually.

G. The NetKonnect Remote Monitor (QP-983P)

78. Nihon Kohden's NetKonnect Remote Monitor (a/k/a QP-983P) allows users to "review real-time patient data from any PC in the hospital or online via a secure Web browser." Nihon Kohden, NetKonnect, *available at* https://us.nihonkohden.com/products/netkonnect/. "Just like a monitor, the NetKonnect interface shows clear waveforms and patient data—12-lead ECG, full disclosure ECG, arrhythmia and ST recall, trends and other information." *Id*. A true and accurate copy of Nihon Kohden's marketing brochure for the NetKonnect Remote Monitor is attached hereto as **Exhibit K**.

79. The NetkKonnect Remote Monitor received 510(k) clearance in 2011. Since then, it has undergone substantial changes regarding it software, user interface, functionality, and intended use. Such changes, include, but are not limited to, increasing the number of supported beds from 1000 to 2000, adding new features to the device, and continuously changing and upgrading the device's software.

80. Given these significant changes and modifications, Nihon Kohden was required to file a premarket notification submission with the FDA seeking an updated, "catch-up" 510(k) clearance for the NetKonnect Remote Monitor. But instead, Nihon Kohden simply added an internal LTF for all of these changes. None of these changes were submitted or reviewed by the FDA, yet Nihon Kohden nevertheless introduced marketed, distributed and sold the adulterated/misbranded NetKonnect Remote Monitor. To this day, Nihon Kohden is still marketing and selling the NetKonnect Remote Monitor without an updated, catch-up 510(k) clearance.

81. The NetKonnect Remote Monitor has been on the market for over seven years and costs approximately $20,000 (plus license fee).

H. The ViTrac Mobile Application

82. The ViTrac Mobile Application is a mobile application ("app") that "provides a secure method for monitoring and viewing a wide range of Nihon Kohden generated patient data." Nihon Kohden, ViTrac, *available at* https://us.nihonkohden.com/products/vitrac/. "Patient data can be viewed in real-time on Apple's mobile iOS devices within

the hospital network or remotely, via a VPN connection." *Id*. According to Nihon, "[t]he mobile application provides a robust and easy to use interface which allows users to see current waveforms, vital signs, stored data and much more." *Id*.

83. The ViTrac Mobile Application is the type of mobile app on which the FDA expressly focusses its regulatory oversight. In particular, the FDA has stated that such mobile applications that are used "in active patient monitoring" or for analyzing medical data must comply with federal rules and regulations. *Mobile Medical Applications: Guidance for Industry and Food and Drug Administration Staff*, U.S. Dep't of Health and Human Services Food and Drug Administration (Feb. 9, 2015), *available at* https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf. This includes mobile applications that provide a "remote display of data from bedside monitors"—indeed, "mobile medical apps that display medical data to perform active patient monitoring such as bedside monitors are subject to regulations associated with such devices." *Id*. at 14. That is because these mobile applications "are medical devices whose functionality could pose a risk to a patient's safety if the mobile app were to not function as intended." *Id*. at 4.

84. As a device used in active patient monitoring and for analyzing medical data, the ViTrac Mobile Application is subject to the same federal rules and regulations as those medical devices that transmit data to the app. If the ViTrac Mobile Application were to not function as intended, patients would be subject to great risk. As a result, Nihon Kohden was required to file a premarket notification submission with the FDA seeking 510(k) clearance for the ViTrac Mobile Application

85. To date, however, the ViTrac Mobile Application has no 510(k) clearance and has undergone no FDA review. Instead, Nihon Kohden simply added an internal document to its files, stating that the ViTrac Mobile Application was not used in active patient monitoring and, therefore, did not need 510(k) clearance. This determination is wrong because the ViTrac Mobile Application is in fact used in active patient monitoring.

86. In addition, the ViTrac Mobile Application has undergone significant

software, design, and functionality changes, as well as revisions to the app's operating manual. Despite these changes, Nihon Kohden never sought 510(k) clearance for the ViTrac Mobile Application. To this day, Nihon Kohden is still marketing and selling the ViTrac Mobile Application without any 510(k) clearance whatsoever.

87. The Vitrac Mobile Application costs approximately $20,000 (plus license fee).

* * * * *

88. With respect to all of these devices, Nihon Kohden knew that the Monitoring Devices either did not have the same intended use as their predicates (including off-label uses), had different technological characteristics (including significant hardware and software alterations), raised safety and efficacy issues, and—in many cases—lacked 510(k) clearance altogether. As a result, the Monitoring Devices all needed their own independent 510(k) clearance (if not a wholly new and separate FDA premarket approval) or an updated, catch-up 510(k). Nihon Kohden did neither, yet still introduced the Monitoring Devices into interstate commerce.

89. Nihon Kohden has received multiple complaints from consumers regarding these Monitoring Devices. For example, Nihon Kohden has received constant complaints of communication losses amongst devices, where patient data and information is not being reported from device to device. Nihon Kohden has also received complaints about devices failing due to software upgrades. This is because Nihon Kohden rushes its Monitoring Devices to market without first conducting adequate testing.

90. For example, upon information and belief, when Nihon Kohden sold and installed Monitoring Devices that subsequently failed at the Trinity Health St. Alphonsus Medical Center in Boise, Idaho, a hospital representative complained that Nihon Kohden had used St. Alphonsus as a "guinea pig" for its untested Monitoring Devices.

91. Another example, upon further information and belief, a patient at a hospital in Pennsylvania reportedly died because a ZM series tele-transmitter that was monitoring the patient's vitals failed to alarm when the patient's condition became critical. A civil

action against the hospital has been filed on behalf of the decedent's estate.

92. Because these devices are all adulterated/misbranded/off-label, Nihon Kohden never once submitted any of these complaints to the FDA. Had Nihon Kohden done so, it would have notified the FDA that it was marketing and distributing adulterated/misbranded/off-label devices. As a result, numerous consumer complaints go unreported each year.

93. In fact, Nihon Kohden has even recalled several Monitoring Devices in response to consumer complaints. For example, one significant recall in 2016 was against the RNS-9703 product—which never received 510(k) clearance, only an internal LTF. But once again, because these Monitoring Devices are all adulterated/misbranded/off-label and not filed with the FDA, these recalls go unreported as well.

94. This type of fraud has been occurring at Nihon Kohden for many years and is pervasive across its entire business. Multiple employees, including Relators, have voiced concerns about the LTF process to Nihon Kohden's leadership. Mr. Finch has reported these specific issues to Nihon Kohden's Vice President of Human Resources, who wholly ignored this issue and declined to perform any investigation into the various adulterated/misbranded/off-label devices. In many research and development meetings, various product managers and senior engineers would also state that alterations of these devices require new 510(k) submissions with the FDA, rather than an internal LTF. All of these concerns have been ignored, and Nihon Kohden still continues its fraud to this day.

95. As further evidence of this corporate-wide fraud, Nihon Kohden has gone through 4–5 Directors of Quality Assurance in the past 5 years. Upon information and belief, the current Director of Quality Assurance resigned in October 2018 after raising concerns over the several thousands of product complaints that have gone unreported to the FDA and about Nihon Kohden's non-compliance with the 510(k) process. Upon information and belief, the Director stated that she "***was not going to jail for this company***."

96. At all relevant times, Nihon Kohden knew that the Government routinely paid hospitals for their use of the Monitoring Devices. Thus, Nihon Kohden knew that the Government would receive numerous claims for reimbursement for their Monitoring Devices. Nihon Kohden also knew that the fact that the Monitoring Devices were adulterated/misbranded/off-label was material to the Government's (including all federal and state funded healthcare programs) payment decisions. Had the Government known that the Monitoring Devices were adulterated/misbranded/off-label and lacked FDA clearance, the Government would not have paid the reimbursement claims. Consequently, every claim presented to the Government for use of a Monitoring Device was a false claim, and each claim was knowingly caused by Nihon Kohden.

97. The damages incurred by the Government as a result of the foregoing fraud are substantial. This fraud impacts all Government agencies that made any payment for use of a Monitoring Device, including all reimbursement claims paid by federal and state healthcare programs, as well as all payments made pursuant to any federal defense contracts. Relators estimate that, since 2012, the Government has improperly paid tens of millions of dollars in false claims for the adulterated/misbranded/off-label Monitoring Devices.

COUNT ONE

VIOLATION OF THE FALSE CLAIMS ACT

31 U.S.C. § 3729(a)(1)(A)

98. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

99. As set forth above, from at least 2012 through the present, Defendants presented false or fraudulent claims for payment, or knowingly caused false or fraudulent claims for payment to be presented, to officials of the United States Government in violation of 31 U.S.C. § 3729(a)(1)(A).

100. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the United States suffered actual damages and therefore is entitled to

multiple damages under the False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT TWO

VIOLATION OF THE FALSE CLAIMS ACT

31 U.S.C. § 3729(a)(1)(B)

101. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

102. As set forth above, from at least 2012 through the present, Defendants knowingly made, used, or caused to be made or used false records or statements material to false or fraudulent claims in violation of 31 U.S.C. § 3729(a)(1)(B). Defendants knowingly and falsely certified that its claims for reimbursement complied with all applicable laws and regulations.

103. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the United States suffered actual damages and therefore is entitled to multiple damages under the False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT THREE

VIOLATION OF THE FALSE CLAIM ACT

31 U.S.C. 3729(a)(1)(C)

104. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as through fully set forth herein.

105. As set forth above, from at least 2012 through the present, Defendants knowingly conspired to commit a violation of the False Claims Act in violation of 31 U.S.C. §3729(a)(1)(C).

106. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the United States suffered actual damages and therefore is entitled to multiple damages under the False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT FOUR

VIOLATION OF THE ALASKA MEDICAL ASSISTANCE FALSE CLAIMS AND REPORTING ACT

ALASKA STAT. § 09.58.010(a)(1)

107. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

108. This is a claim for penalties and treble damages under the Alaska Medical Assistance False Claims and Reporting Act.

109. As set forth above, from at least 2011 through the present, Defendants knowingly presented or caused to be presented to the State of Alaska false or fraudulent claims for payment or approval in violation of Alaska Stat. § 09.58.010(a)(1).

110. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Alaska suffered actual damages and therefore is entitled to multiple damages under the Alaska Medical Assistance False Claims and Reporting Act, to be determined at trial, plus a civil penalty for each violation.

COUNT FIVE

VIOLATION OF THE ALASKA MEDICAL ASSISTANCE FALSE CLAIMS AND REPORTING ACT

ALASKA STAT. § 09.58.010(a)(2)

111. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

112. This is a claim for penalties and treble damages under Alaska Medical Assistance False Claims and Reporting Act.

113. As set forth above, from at least 2011 through the present, Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim submitted to the State of Alaska in violation of in violation of Alaska Stat. § 09.58.010(a)(2).

114. By virtue of the false or fraudulent claims submitted or caused to be submitted

by Defendants, the State of Alaska suffered actual damages and therefore is entitled to multiple damages under the Alaska Medical Assistance False Claims and Reporting Act, to be determined at trial, plus a civil penalty for each violation.

COUNT SIX

VIOLATION OF THE ALASKA MEDICAL ASSISTANCE FALSE CLAIMS AND REPORTING ACT

ALASKA STAT. § 09.58.010(a)(3)

115. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

116. This is a claim for penalties and treble damages under the Alaska Medical Assistance False Claims and Reporting Act.

117. As set forth above, from at least 2011 through the present, Defendants knowingly conspired together to commit violations of the Alaska Medical Assistance False Claims and Reporting Act in violation of Alaska Stat. § 09.58.010(a)(3).

118. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Alaska suffered actual damages and therefore is entitled to multiple damages under the Alaska Medical Assistance False Claims and Reporting Act, to be determined at trial, plus a civil penalty for each violation.

COUNT SEVEN

VIOLATION OF THE CALIFORNIA FALSE CLAIMS ACT

CAL. GOV'T CODE § 12651(A)(1)

119. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

120. This is a claim for penalties and treble damages under the California False Claims Act.

121. As set forth above, from at least 2011 through the present, Defendants knowingly presented or caused to be presented to the State of California false or fraudulent claims for payment or approval in violation of Cal. Gov't Code §12651(A)(1).

122. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of California suffered actual damages and therefore is entitled to multiple damages under the California False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT EIGHT

VIOLATION OF THE CALIFORNIA FALSE CLAIMS ACT

CAL. GOV'T CODE § 12651(A)(2)

123. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

124. This is a claim for penalties and treble damages under the California False Claims Act.

125. As set forth above, from at least 2011 through the present, Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim submitted to the State of California in violation of in violation of Cal. Gov't Code §12651(A)(2).

126. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of California suffered actual damages and therefore is entitled to multiple damages under the California False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT NINE

VIOLATION OF THE CALIFORNIA FALSE CLAIMS ACT

CAL. GOV'T CODE § 12651(A)(3)

127. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

128. This is a claim for penalties and treble damages under the California False Claims Act.

129. As set forth above, from at least 2011 through the present, Defendants knowingly conspired together to commit violations of the California False Claims Act in

violation of Cal. Gov't Code §12651(A)(3).

130. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of California suffered actual damages and therefore is entitled to multiple damages under the California False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT TEN

VIOLATION OF THE COLORADO MEDICAID FALSE CLAIMS ACT

COLO. REV. STAT. §25.5-4-305(1)(a)

131. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

132. This is a claim for penalties and treble damages under the Colorado Medicaid False Claims Act.

133. As set forth above, from at least 2011 through the present, Defendants knowingly presented or caused to be presented to the State of Colorado false or fraudulent claims for payment or approval in violation of Colo. Rev. Stat. §25.5-4-305(1)(a).

134. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Colorado suffered actual damages and therefore is entitled to multiple damages under the Colorado Medicaid False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT ELEVEN

VIOLATION OF THE COLORADO MEDICAID FALSE CLAIMS ACT

COLO. REV. STAT. §25.5-4-305(1)(b)

135. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

136. This is a claim for penalties and treble damages under the Colorado Medicaid False Claims Act.

137. As set forth above, from at least 2011 through the present, Defendants knowingly made, used, or caused to be made or used false records or statements material

to a false or fraudulent claim submitted to the State of Colorado in violation of Colo. Rev. Stat. §25.5-4-305(1)(b).

138. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Colorado suffered actual damages and therefore is entitled to multiple damages under the Colorado Medicaid False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT TWELVE

VIOLATION OF THE COLORADO MEDICAID FALSE CLAIMS ACT

COLO. REV. STAT. §25.5-4-305(1)(g)

139. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

140. This is a claim for penalties and treble damages under the Colorado Medicaid False Claims Act.

141. As set forth above, from at least 2011 through the present, Defendants knowingly conspired together to commit violations of the Colorado Medicaid False Claims Act in violation of Colo. Rev. Stat. §25.5-4-305(1)(g).

142. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Colorado suffered actual damages and therefore is entitled to multiple damages under the Colorado Medicaid False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT THIRTEEN

VIOLATION OF THE CONNECTICUT FALSE CLAIMS

CONN GEN. STAT. §4-275(1)

143. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

144. This is a claim for penalties and treble damages under the Connecticut False Claims Act.

145. As set forth above, from at least 2011 through the present, Defendants

knowingly presented or caused to be presented to the State of Connecticut false or fraudulent claims for payment or approval in violation of Conn. Gen. Stat. §4-275(1).

146. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Connecticut suffered actual damages and therefore is entitled to multiple damages under the Connecticut False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT FOURTEEN

VIOLATION OF THE CONNECTICUT FALSE CLAIMS ACT

CONN. GEN. STAT. §4-275(2)

147. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

148. This is a claim for penalties and treble damages under the Connecticut False Claims Act.

149. As set forth above, from at least 2011 through the present, Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim submitted to the State of Connecticut in violation of Conn. Gen. Stat. §4-275(2).

150. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Connecticut suffered actual damages and therefore is entitled to multiple damages under the Connecticut False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT FIFTEEN

VIOLATION OF THE CONNECTICUT FALSE CLAIMS ACT

CONN. GEN. STAT. §4-275(3)

151. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

152. This is a claim for penalties and treble damages under the Connecticut False Claims Act for Medical Assistance Programs.

153. As set forth above, from at least 2011 through the present, Defendants knowingly conspired together to commit violations of the Connecticut False Claims Act in violation of Conn. Gen. Stat. §4-275(3).

154. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Connecticut suffered actual damages and therefore is entitled to multiple damages under the Connecticut False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT SIXTEEN

VIOLATION OF THE DELAWARE FALSE CLAIMS AND REPORTING ACT

DEL. CODE ANN. § 1201(a)(1)

155. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

156. This is a claim for penalties and treble damages under the Delaware False Claims and Reporting Act.

157. As set forth above, from at least 2011 through the present, Defendants knowingly presented or caused to be presented to the State of Delaware false or fraudulent claims for payment or approval in violation of Del. Code Ann. §1201(a)(1)

158. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Delaware suffered actual damages and therefore is entitled to multiple damages under the Delaware False Claims and Reporting Act, to be determined at trial, plus a civil penalty for each violation.

COUNT SEVENTEEN

VIOLATION OF THE DELAWARE FALSE CLAIMS AND REPORTING ACT

DEL. CODE ANN. §1201(a)(2)

159. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

160. This is a claim for penalties and treble damages under the Delaware False Claims and Reporting Act.

161. As set forth above, from at least 2011 through the present, Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim submitted to the State of Delaware in violation of Del. Code Ann. §1201(a)(2).

162. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Delaware suffered actual damages and therefore is entitled to multiple damages under the Delaware False Claims and Reporting Act, to be determined at trial, plus a civil penalty for each violation.

COUNT EIGHTEEN

VIOLATION OF THE DELAWARE FALSE CLAIMS AND REPORTING ACT

DEL. CODE ANN. §1201(a)(3)

163. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

164. This is a claim for penalties and treble damages under the Delaware False Claims and Reporting Act.

165. As set forth above, from at least 2011 through the present, Defendants knowingly conspired together to commit violations of the Delaware False Claims and Reporting Act in violation of Del. Code Ann. §1201(a)(3).

166. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Delaware suffered actual damages and therefore is entitled to multiple damages under the Delaware False Claims and Reporting Act, to be determined at trial, plus a civil penalty for each violation.

COUNT NINETEEN

VIOLATION OF THE DISTRICT OF COLUMBIA FALSE CLAIMS ACT

D.C. CODE §2-381.02(a)(1)

167. Relators incorporate by reference the allegations set forth in the foregoing

paragraphs as though fully set forth herein.

168. This is a claim for penalties and treble damages under the District of Columbia False Claims Act.

169. As set forth above, from at least 2011 through the present, Defendants knowingly presented or caused to be presented to the District of Columbia false or fraudulent claims for payment or approval in violation of D.C. Code. §2-381.02(a)(1).

170. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the District of Columbia suffered actual damages and therefore is entitled to multiple damages under the District of Columbia False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT TWENTY

VIOLATION OF THE DISTRICT OF COLUMBIA FALSE CLAIMS ACT

D.C. CODE §2-381.02(a)(2)

171. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

172. This is a claim for penalties and treble damages under the District of Columbia False Claims Act.

173. As set forth above, from at least 2011 through the present, Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim submitted to the District of Columbia in violation of D.C. Code §2-381.02(a)(2).

174. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the District of Columbia suffered actual damages and therefore is entitled to multiple damages under the District of Columbia False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT TWENTY-ONE

VIOLATION OF THE DISTRICT OF COLUMBIA FALSE CLAIMS ACT

D.C. CODE §2-381.02(a)(3)

175. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

176. This is a claim for penalties and treble damages under the District of Columbia False Claims Act.

177. As set forth above, from at least 2011 through the present, Defendants knowingly conspired together to commit violations of the District of Columbia False Claims Act in violation of D.C. Code §2-381.02(a)(3).

178. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the District of Columbia suffered actual damages and therefore is entitled to multiple damages under the District of Columbia False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT TWENTY-TWO

VIOLATION OF THE FLORIDA FALSE CLAIMS ACT

FLA. STAT. §68.082(2)(a)

179. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

180. This is a claim for penalties and treble damages under the Florida False Claims Act.

181. As set forth above, from at least 2011 through the present, Defendants knowingly presented or caused to be presented to the State of Florida false or fraudulent claims for payment or approval in violation of Fla. Stat. §68.082(2)(a).

182. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Florida suffered actual damages and therefore is entitled to multiple damages under the Florida False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT TWENTY-THREE

VIOLATION OF THE FLORIDA FALSE CLAIMS ACT

FLA. STAT. §68.082(2)(b)

183. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

184. This is a claim for penalties and treble damages under the Florida False Claims Act.

185. As set forth above, from at least 2011 through the present, Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim submitted to the State of Florida in violation of Fla. Stat. §68.082(2)(b).

186. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Florida suffered actual damages and therefore is entitled to multiple damages under the Florida False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT TWENTY-FOUR

VIOLATION OF THE FLORIDA FALSE CLAIMS ACT

FLA. STAT. §68.082(2)(c)

187. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

188. This is a claim for penalties and treble damages under the Florida False Claims Act.

189. As set forth above, from at least 2011 through the present, Defendants knowingly conspired together to commit violations of the Florida False Claims Act in violation of Fla. Stat. §68.082(2)(c).

190. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Florida suffered actual damages and therefore is entitled to multiple damages under the Florida False Claims Act, to be determined at trial, plus a civil

penalty for each violation.

COUNT TWENTY-FIVE

VIOLATION OF THE GEORGIA STATE FALSE MEDICAID CLAIMS ACT

GA. CODE ANN. §49-4-168.1(a)(1)

191. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

192. This is a claim for penalties and treble damages under the Georgia State False Medicaid Claims Act.

193. As set forth above, from at least 2011 through the present, Defendants knowingly presented or caused to be presented to the State of Georgia false or fraudulent claims for payment or approval in violation of Ga. Code Ann. §49-4-168.1(a)(1).

194. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Georgia suffered actual damages and therefore is entitled to multiple damages under the Georgia State False Medicaid Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT TWENTY-SIX

VIOLATION OF THE GEORGIA STATE FALSE MEDICAID CLAIMS ACT

GA. CODE ANN. §49-4-168.1(a)(2)

195. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

196. This is a claim for penalties and treble damages under the Georgia State False Medicaid Claims Act.

197. As set forth above, from at least 2011 through the present, Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim submitted to the State of Georgia in violation of Ga. Code Ann. §49-4-168.1(a)(2).

198. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Georgia suffered actual damages and therefore is entitled to

multiple damages under the Georgia State False Medicaid Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT TWENTY-SEVEN

VIOLATION OF THE GEORGIA STATE FALSE MEDICAID CLAIMS ACT

GA. CODE ANN. §49-4-168.1(a)(3)

199. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

200. This is a claim for penalties and treble damages under the Georgia State False Medicaid Claims Act.

201. As set forth above, from at least 2011 through the present, Defendants knowingly conspired together to commit violations of the Georgia State False Medicaid Claims Act in violation of Ga. Code Ann. §49-4-168.1(a)(3).

202. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Georgia suffered actual damages and therefore is entitled to multiple damages under the Georgia State False Medicaid Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT TWENTY-EIGHT

VIOLATION OF THE HAWAII FALSE CLAIMS ACT

HAW. REV. STAT. §661-21(a)(1)

203. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

204. This is a claim for penalties and treble damages under the Hawaii False Claims Act.

205. As set forth above, from at least 2011 through the present, Defendants knowingly presented or caused to be presented to the State of Hawaii false or fraudulent claims for payment or approval in violation of Haw. Rev. Stat. §661.21(a)(1).

206. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Hawaii suffered actual damages and therefore is entitled to

multiple damages under the Hawaii False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT TWENTY-NINE

VIOLATION OF THE HAWAII FALSE CLAIMS ACT

HAW. REV. STAT. §661-21(a)(2)

207. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

208. This is a claim for penalties and treble damages under the Hawaii False Claims Act.

209. As set forth above, from at least 2011 through the present, Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim submitted to the State of Hawaii in violation of Haw. Rev. Stat. §661-21(a)(2).

210. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Hawaii suffered actual damages and therefore is entitled to multiple damages under the Hawaii False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT THIRTY

VIOLATION OF THE HAWAII FALSE CLAIMS ACT

HAW. REV. STAT. §661-21(a)(8)

211. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

212. This is a claim for penalties and treble damages under the Hawaii False Claims Act.

213. As set forth above, from at least 2011 through the present, Defendants knowingly conspired together to commit violations of the Hawaii False Claims Act in violation of Haw. Rev. Stat. §661-21(a)(8).

214. By virtue of the false or fraudulent claims submitted or caused to be submitted

by Defendants, the State of Hawaii suffered actual damages and therefore is entitled to multiple damages under the Hawaii False Claims Act, to be determined at trial, plus a civil penalty for each violation

COUNT THIRTY-ONE

VIOLATION OF THE ILLINOIS WHISTLEBLOWER REWARD AND PROTECTION ACT

740 ILL. COMP. STAT. §175/3(a)(1)(A)

215. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

216. This is a claim for penalties and treble damages under the Illinois Whistleblower and Protection Act.

217. As set forth above, from at least 2011 through the present, Defendants knowingly presented or caused to be presented to the State of Illinois false or fraudulent claims for payment or approval in violation of 740 Ill. Comp. Stat. §175/3(a)(1)(A).

218. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Illinois suffered actual damages and therefore is entitled to multiple damages under the Illinois Whistleblower and Protection Act, to be determined at trial, plus a civil penalty for each violation.

COUNT THIRTY-TWO

VIOLATION OF THE ILLINOIS WHISTLEBLOWER REWARD AND PROTECTION ACT

740 ILL. COMP. STAT. §175/3(a)(1)(B)

219. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

220. This is a claim for penalties and treble damages under the Illinois Whistleblower and Protection Act.

221. As set forth above, from at least 2011 through the present, Defendants knowingly made, used, or caused to be made or used false records or statements material

to a false or fraudulent claim submitted to the State of Illinois in violation of 740 Ill. Comp. Stat. §175/3(a)(1)(B).

222. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Illinois suffered actual damages and therefore is entitled to multiple damages under the Illinois Whistleblower and Protection Act, to be determined at trial, plus a civil penalty for each violation.

COUNT THIRTY-THREE

VIOLATION OF THE ILLINOIS WHISTLEBLOWER REWARD AND PROTECTION ACT

740 ILL. COMP. STAT. §175/3(a)(1)(C)

223. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

224. This is a claim for penalties and treble damages under the Illinois Whistleblower and Protection Act.

225. As set forth above, from at least 2011 through the present, Defendants knowingly conspired together to commit violations of the Illinois Whistleblower and Protection Act in violation of 740 Ill. Comp. Stat. §175/3(a)(1)(C).

226. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Illinois suffered actual damages and therefore is entitled to multiple damages under the Illinois Whistleblower and Protection Act, to be determined at trial, plus a civil penalty for each violation.

COUNT THIRTY-FOUR

VIOLATION OF THE INDIANA FALSE CLAIMS AND WHISTLEBLOWER PROTECTION ACT

IND. CODE §5-11-5.5-2(b)(1) & (8)

227. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

228. This is a claim for penalties and treble damages under the Indiana False

Claims and Whistleblower Protection Act.

229. As set forth above, from at least 2011 through the present, Defendants knowingly presented or caused to be presented to the State of Indiana false or fraudulent claims for payment or approval in violation of Ind. Code. §5-11-5.5-2(b)(1) & (8).

230. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Indiana suffered actual damages and therefore is entitled to multiple damages under the Indiana False Claims and Whistleblower Protection Act, to be determined at trial, plus a civil penalty for each violation.

COUNT THIRTY-FIVE

VIOLATION OF THE INDIANA FALSE CLAIMS AND WHISTLEBLOWER PROTECTION ACT

IND. CODE §5-11-5.5-2(b)(2) & (8)

231. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

232. This is a claim for penalties and treble damages under the Indiana False Claims and Whistleblower Protection Act.

233. As set forth above, from at least 2011 through the present, Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim submitted to the State of Indiana in violation of Ind. Code §5-11-5.5-2(b)(2) & (8).

234. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Indiana suffered actual damages and therefore is entitled to multiple damages under the Indiana False Claims and Whistleblower Protection Act, to be determined at trial, plus a civil penalty for each violation.

COUNT THIRTY-SIX

VIOLATION OF THE INDIANA FALSE CLAIMS AND WHISTLEBLOWER PROTECTION ACT

IND. CODE §5-11-5.5-2(b)(7)

235. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

236. This is a claim for penalties and treble damages under the Indiana False Claims and Whistleblower Protection Act.

237. As set forth above, from at least 2011 through the present, Defendants knowingly conspired together to commit violations of the Indiana False Claims and Whistleblower Protection Act in violation of Ind. Code §5-11-5.5-2(b)(7).

238. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Indiana suffered actual damages and therefore is entitled to multiple damages under the Indiana False Claims and Whistleblower Protection Act, to be determined at trial, plus a civil penalty for each violation.

COUNT THIRTY-SEVEN

VIOLATION OF THE IOWA FALSE CLAIMS ACT

IOWA CODE §685.2(1)(a)

239. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

240. This is a claim for penalties and treble damages under the Iowa False Claims Act.

241. As set forth above, from at least 2011 through the present, Defendants knowingly presented or caused to be presented to the State of Iowa false or fraudulent claims for payment or approval in violation of Iowa Code §685.2(1)(a).

242. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Iowa suffered actual damages and therefore is entitled to multiple damages under the Iowa False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT THIRTY-EIGHT

VIOLATION OF THE IOWA FALSE CLAIMS ACT

IOWA CODE §685.2(1)(b)

243. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

244. This is a claim for penalties and treble damages under the Iowa False Claims Act.

245. As set forth above, from at least 2011 through the present, Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim submitted to the State of Iowa in violation of Iowa Code §685.2(1)(b).

246. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Iowa suffered actual damages and therefore is entitled to multiple damages under the Iowa False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT THIRTY-NINE

VIOLATION OF THE IOWA FALSE CLAIMS ACT

IOWA CODE §685.2(1)(c)

247. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

248. This is a claim for penalties and treble damages under the Iowa False Claims Act.

249. As set forth above, from at least 2011 through the present, Defendants knowingly conspired together to commit violations of the Iowa False Claims Act in violation of Iowa Code §685.2(1)(c).

250. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Iowa suffered actual damages and therefore is entitled to multiple damages under the Iowa False Claims Act, to be determined at trial, plus a civil

penalty for each violation.

COUNT FORTY

VIOLATION OF THE LOUISIANA MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW

LA. STAT. ANN. §46:438.3(A)

251. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

252. This is a claim for penalties and treble damages under the Louisiana Medical Assistance Programs Integrity Law.

253. As set forth above, from at least 2011 through the present, Defendants knowingly presented or caused to be presented to the State of Louisiana false or fraudulent claims for payment or approval in violation of La. Stat. Ann. §46:438.3(A).

254. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Louisiana suffered actual damages and therefore is entitled to multiple damages under the Louisiana Medical Assistance Programs Integrity Law, to be determined at trial, plus a civil penalty for each violation.

COUNT FORTY-ONE

VIOLATION OF THE LOUISIANA MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW

LA. STAT. ANN. §46:438.3(B)

255. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

256. This is a claim for penalties and treble damages under the Louisiana Medical Assistance Programs Integrity Law.

257. As set forth above, from at least 2011 through the present, Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim submitted to the State of Louisiana in violation of La. Stat. Ann. §46:438.3(B).

258. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Louisiana suffered actual damages and therefore is entitled to multiple damages under the Louisiana Medical Assistance Programs Integrity Law, to be determined at trial, plus a civil penalty for each violation.

COUNT FORTY-TWO

VIOLATION OF THE LOUISIANA MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW

LA. STAT. ANN. §46:438.3(D)

259. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

260. This is a claim for penalties and treble damages under the Louisiana Medical Assistance Programs Integrity Law.

261. As set forth above, from at least 2011 through the present, Defendants knowingly conspired together to commit violations of the Louisiana Medical Assistance Programs Integrity Law in violation of La. Stat. Ann. §46:438.3(D).

262. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Louisiana suffered actual damages and therefore is entitled to multiple damages under the Louisiana Medical Assistance Programs Integrity Law, to be determined at trial, plus a civil penalty for each violation.

COUNT FORTY-THREE

VIOLATION OF THE LOUISIANA MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW

LA. STAT. ANN. §46:438.2(A)

263. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

264. This is a claim for penalties and treble damages under the Louisiana Medical Assistance Programs Integrity Law.

265. As set forth above, from at least 2011 through the present, Defendants

knowingly solicited, received, offered, and paid remuneration in return for purchasing and ordering goods for which payment may be made under Louisiana's Medical Assistance Program in violation of La. Stat. § 46:438.2(A).

266. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Louisiana suffered actual damages and therefore is entitled to multiple damages under the Louisiana Medical Assistance Programs Integrity Law, to be determined at trial, plus a civil penalty for each violation.

COUNT FORTY-FOUR

VIOLATION OF THE MARYLAND FALSE CLAIMS ACT

MD. CODE ANN., Health – Gen., §2-602(a)(1)

267. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

268. This is a claim for penalties and treble damages under the Maryland False Claims Act.

269. As set forth above, from at least 2011 through the present, Defendants knowingly presented or caused to be presented to the State of Maryland false or fraudulent claims for payment or approval in violation of MD. Code Ann., Health – Gen., §2-702(a)(1).

270. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Maryland suffered actual damages and therefore is entitled to multiple damages under the Maryland False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT FORTY-FIVE

VIOLATION OF THE MARYLAND FALSE CLAIMS ACT

MD. CODE ANN., Health – Gen., §2-602(a)(2)

271. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

272. This is a claim for penalties and treble damages under the Maryland False

Claims Act.

273. As set forth above, from at least 2011 through the present, Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim submitted to the State of Maryland in violation of MD. Code Ann., Health – Gen., §2-602(a)(2).

274. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Maryland suffered actual damages and therefore is entitled to multiple damages under the Maryland False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT FORTY-SIX

VIOLATION OF THE MARYLAND FALSE CLAIMS ACT

MD. CODE ANN., Health – Gen., §2-602(a)(3)

275. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

276. This is a claim for penalties and treble damages under the Maryland False Claims Act.

277. As set forth above, from at least 2011 through the present, Defendants knowingly conspired together to commit violations of the Maryland False Claims Act in violation of MD Code Ann., Health – Gen., §2-601(a)(3).

278. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Maryland suffered actual damages and therefore is entitled to multiple damages under the Maryland False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT FORTY-SEVEN

VIOLATION OF THE MASSACHUSETTS FALSE CLAIMS ACT

MASS. GEN. LAWS, ch. 12, § 5B(a)(1)

279. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

280. This is a claim for penalties and treble damages under the Massachusetts False Claims Act.

281. As set forth above, from at least 2011 through the present, Defendants knowingly presented or caused to be presented to the Commonwealth of Massachusetts false or fraudulent claims for payment or approval in violation of Mass. Gen. Laws, ch. 12, §5B(a)(1).

282. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the Commonwealth of Maryland suffered actual damages and therefore is entitled to multiple damages under the Massachusetts False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT FORTY-EIGHT

VIOLATION OF THE MASSACHUSETTS FALSE CLAIMS ACT

MASS. GEN. LAWS, ch. 12, § 5B(a)(2)

283. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

284. This is a claim for penalties and treble damages under the Massachusetts False Claims Act.

285. As set forth above, from at least 2011 through the present, Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim submitted to the Commonwealth of Massachusetts in violation of Mass. Gen. Laws, ch. 12, §5B(a)(2).

286. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the Commonwealth of Massachusetts suffered actual damages and therefore is entitled to multiple damages under the Massachusetts False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT FORTY-NINE

VIOLATION OF THE MASSACHUSETTS FALSE CLAIMS ACT

MASS. GEN. LAWS, ch. 12, § 5B(a)(3)

287. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

288. This is a claim for penalties and treble damages under the Massachusetts False Claims Act.

289. As set forth above, from at least 2011 through the present, Defendants knowingly conspired together to commit violations of the Massachusetts False Claims Act in violation of Mass. Gen. Laws, ch. 12, §5B(a)(3).

290. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the Commonwealth suffered actual damages and therefore is entitled to multiple damages under the Massachusetts False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT FIFTY

VIOLATION OF THE MICHIGAN MEDICAID FALSE CLAIMS ACT

MICH. COMP. LAWS § 400.607(1)

291. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

292. This is a claim for penalties and treble damages under the Michigan Medicaid False Claims Act.

293. As set forth above, from at least 2011 through the present, Defendants knowingly presented or caused to be presented to the State of Michigan false or fraudulent claims for payment or approval in violation of Mich. Comp. Laws §400.607(1).

294. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Michigan suffered actual damages and therefore is entitled to multiple damages under the Michigan Medicaid False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT FIFTY-ONE

VIOLATION OF THE MICHIGAN MEDICAID FALSE CLAIMS ACT

MICH. COMP. LAWS § 400.607(2)

295. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

296. This is a claim for penalties and treble damages under the Michigan Medicaid False Claims Act.

297. As set forth above, from at least 2011 through the present, Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim submitted to the State of Michigan in violation of Mich. Comp. Laws §400.607(2).

298. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Michigan suffered actual damages and therefore is entitled to multiple damages under the Michigan Medicaid False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT FIFTY-TWO

VIOLATION OF THE MICHIGAN MEDICAID FALSE CLAIMS ACT

MICH. COMP. LAWS § 400.606(1)

299. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

300. This is a claim for penalties and treble damages under the Michigan Medicaid False Claims Act.

301. As set forth above, from at least 2011 through the present, Defendants knowingly conspired together to commit violations of the Michigan Medicaid False Claims Act in violation of Mich. Comp. Laws §400.606(1).

302. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Michigan suffered actual damages and therefore is entitled to multiple damages under the Michigan Medicaid False Claims Act, to be determined at

trial, plus a civil penalty for each violation.

COUNT FIFTY-THREE

VIOLATION OF THE MICHIGAN MEDICAID FALSE CLAIMS ACT

MICH. COMP. LAWS § 400.604

303. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

304. This is a claim for penalties and treble damages under the Michigan Medicaid False Claims Act.

305. As set forth above, from at least 2011 through the present, Defendants knowingly solicited, offered, and/or received kickbacks or bribes in connection with the furnishing of goods for which payment may be made by the State of Michigan in violation of Mich. Comp. Laws §400.604.

306. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Michigan suffered actual damages and therefore is entitled to multiple damages under the Michigan Medicaid False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT FIFTY-FOUR

VIOLATION OF THE MINNESOTA FALSE CLAIMS ACT

MINN. STAT. §15C.02(a)(1)

307. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

308. This is a claim for penalties and treble damages under the Minnesota False Claims Act.

309. As set forth above, from at least 2011 through the present, Defendants knowingly presented or caused to be presented to the State of Minnesota false or fraudulent claims for payment or approval in violation of Minn. Stat. §15C.02(a)(1).

310. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Minnesota suffered actual damages and therefore is entitled to

multiple damages under the Minnesota False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT FIFTY-FIVE

VIOLATION OF THE MINNESOTA FALSE CLAIMS ACT

MINN. STAT. §15C.02(a)(2)

311. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

312. This is a claim for penalties and treble damages under the Minnesota False Claims Act.

313. As set forth above, from at least 2011 through the present, Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim submitted to the State of Minnesota in violation of Minn. Stat. §15C.02(a)(2).

314. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Minnesota suffered actual damages and therefore is entitled to multiple damages under the Minnesota False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT FIFTY-SIX

VIOLATION OF THE MINNESOTA FALSE CLAIMS ACT

MINN. STAT. §15C.02(a)(3)

315. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

316. This is a claim for penalties and treble damages under the Minnesota False Claims Act.

317. As set forth above, from at least 2011 through the present, Defendants knowingly conspired together to commit violations of the Minnesota False Claims Act in violation of Minn. Stat. §15C.02(a)(3).

318. By virtue of the false or fraudulent claims submitted or caused to be submitted

by Defendants, the State of Minnesota suffered actual damages and therefore is entitled to multiple damages under the Minnesota False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT FIFTY-SEVEN

VIOLATION OF THE MONTANA FALSE CLAIMS ACT

MONT. CODE ANN. §17-8-403(1)(a)

319. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

320. This is a claim for penalties and treble damages under the Montana False Claims Act.

321. As set forth above, from at least 2011 through the present, Defendants knowingly presented or caused to be presented to the State of Montana false or fraudulent claims for payment or approval in violation of Mont. Code Ann. §17-8-403(1)(a).

322. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Montana suffered actual damages and therefore is entitled to multiple damages under the Montana False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT FIFTY-EIGHT

VIOLATION OF THE MONTANA FALSE CLAIMS ACT

MONT. CODE ANN. §17-8-403(1)(b)

323. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

324. This is a claim for penalties and treble damages under the Montana False Claims Act.

325. As set forth above, from at least 2011 through the present, Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim submitted to the State of Montana in violation of Mont. Code. Ann. §17-8-403(1)(b).

326. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Montana suffered actual damages and therefore is entitled to multiple damages under the Montana False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT FIFTY-NINE

VIOLATION OF THE MONTANA FALSE CLAIMS ACT

MONT. CODE ANN. §17-8-403(1)(c)

327. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

328. This is a claim for penalties and treble damages under the Montana False Claims Act.

329. As set forth above, from at least 2011 through the present, Defendants knowingly conspired together to commit violations of the Montana False Claims Act in violation of Mont. Code Ann. §17-8-403(1)(c).

330. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Montana suffered actual damages and therefore is entitled to multiple damages under the Montana False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT SIXTY

VIOLATION OF THE NEVADA FALSE CLAIMS ACT

NEV. REV. STAT. §357.040(1)(a)

331. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

332. This is a claim for penalties and treble damages under the Nevada False Claims Act.

333. As set forth above, from at least 2011 through the present, Defendants knowingly presented or caused to be presented to the State of Nevada false or fraudulent claims for payment or approval in violation of Nev. Rev. Stat. §357.040(1)(a).

334. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Nevada suffered actual damages and therefore is entitled to multiple damages under the Nevada False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT SIXTY-ONE

VIOLATION OF THE NEVADA FALSE CLAIMS ACT

NEV. REV. STAT. §357.040(1)(b)

335. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

336. This is a claim for penalties and treble damages under the Nevada False Claims Act.

337. As set forth above, from at least 2011 through the present, Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim submitted to the State of Nevada in violation of Nev. Rev. Stat. §357.040(1)(b).

338. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Nevada suffered actual damages and therefore is entitled to multiple damages under the Nevada False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT SIXTY-TWO

VIOLATION OF THE NEVADA FALSE CLAIMS ACT

NEV. REV. STAT. §357.040(1)(i)

339. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

340. This is a claim for penalties and treble damages under the Nevada False Claims Act.

341. As set forth above, from at least 2011 through the present, Defendants knowingly conspired together to commit violations of the Nevada False Claims Act in

violation of Nev. Rev. Stat. §357.040(1)(i).

342. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Nevada suffered actual damages and therefore is entitled to multiple damages under the Nevada False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT SIXTY-THREE

VIOLATION OF THE NEW HAMPSHIRE FALSE CLAIMS ACT

N.H. REV. STAT. ANN. §167:61-b(I)(a)

343. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

344. This is a claim for penalties and treble damages under the New Hampshire False Claims Act.

345. As set forth above, from at least 2011 through the present, Defendants knowingly presented or caused to be presented to the State of New Hampshire false or fraudulent claims for payment or approval in violation of N.H. Rev. Stat. Ann. §167:61-b(I)(a).

346. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of New Hampshire suffered actual damages and therefore is entitled to multiple damages under the New Hampshire False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT SIXTY-FOUR

VIOLATION OF THE NEW HAMPSHIRE FALSE CLAIMS ACT

N.H. REV. STAT. ANN. §167:61-b(I)(b)

347. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

348. This is a claim for penalties and treble damages under the New Hampshire False Claims Act.

349. As set forth above, from at least 2011 through the present, Defendants

knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim submitted to the State of New Hampshire in violation of N.H. Rev. Stat. Ann. §167:61-b(I)(b).

350. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of New Hampshire suffered actual damages and therefore is entitled to multiple damages under the New Hampshire False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT SIXTY-FIVE

VIOLATION OF THE NEW HAMPSHIRE FALSE CLAIMS ACT

N.H. REV. STAT. ANN. §167:61-b(I)(c)

351. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

352. This is a claim for penalties and treble damages under the New Hampshire False Claims Act.

353. As set forth above, from at least 2011 through the present, Defendants knowingly conspired together to commit violations of the New Hampshire False Claims Act in violation of N.H. Rev. Stat. Ann. §167:61-b(I)(c).

354. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of New Hampshire suffered actual damages and therefore is entitled to multiple damages under the New Hampshire False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT SIXTY-SIX

VIOLATION OF THE NEW JERSEY FALSE CLAIMS ACT

N.J. STAT. ANN. §2A:32C-3(a)

355. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

356. This is a claim for penalties and treble damages under the New Jersey False Claims Act.

357. As set forth above, from at least 2011 through the present, Defendants knowingly presented or caused to be presented to the State of New Jersey false or fraudulent claims for payment or approval in violation of N.J. Stat. Ann. §2A:32C-3(a).

358. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of New Jersey suffered actual damages and therefore is entitled to multiple damages under the New Jersey False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT SIXTY-SEVEN

VIOLATION OF THE NEW JERSEY FALSE CLAIMS ACT

N.J. STAT. ANN. §2A:32C-3(b)

359. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

360. This is a claim for penalties and treble damages under the New Jersey False Claims Act.

361. As set forth above, from at least 2011 through the present, Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim submitted to the State of New Jersey in violation of N.J. Stat. Ann. §2A:32C-3(b).

362. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of New Jersey suffered actual damages and therefore is entitled to multiple damages under the New Jersey False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT SIXTY-EIGHT

VIOLATION OF THE NEW JERSEY FALSE CLAIMS ACT

N.J. STAT. ANN. §2A:32C-3(c)

363. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

364. This is a claim for penalties and treble damages under the New Jersey False

Claims Act.

365. As set forth above, from at least 2011 through the present, Defendants knowingly conspired together to commit violations of the New Jersey False Claims Act in violation of N.J. Stat. Ann. §2A:32C-3(c).

366. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of New Jersey suffered actual damages and therefore is entitled to multiple damages under the New Jersey False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT SIXTY-NINE

VIOLATION OF THE NEW MEXICO MEDICAID FALSE CLAIMS ACT

N.M. STAT. ANN. §27-14-4(A)

367. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

368. This is a claim for penalties and treble damages under the New Mexico Medicaid False Claims Act.

369. As set forth above, from at least 2011 through the present, Defendants knowingly presented or caused to be presented to the State of New Mexico false or fraudulent claims for payment or approval in violation of N.M. Stat. Ann. §27-14-4(A).

370. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of New Mexico suffered actual damages and therefore is entitled to multiple damages under the New Mexico Medicaid False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT SEVENTY

VIOLATION OF THE NEW MEXICO MEDICAID FALSE CLAIMS ACT

N.M. STAT. ANN. §27-14-4(C)

371. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

372. This is a claim for penalties and treble damages under the New Mexico

Medicaid False Claims Act.

373. As set forth above, from at least 2011 through the present, Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim submitted to the State of New Mexico in violation of N.M. Stat. Ann. §27-14-4(C).

374. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of New Mexico suffered actual damages and therefore is entitled to multiple damages under the New Mexico Medicaid False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT SEVENTY-ONE

VIOLATION OF THE NEW MEXICO MEDICAID FALSE CLAIMS ACT

N.M. STAT. ANN. §27-14-4(D)

375. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

376. This is a claim for penalties and treble damages under the New Mexico Medicaid False Claims Act.

377. As set forth above, from at least 2011 through the present, Defendants knowingly conspired together to commit violations of the New Mexico Medicaid False Claims Act in violation of N.M. Stat. Ann. §27-14-4(D).

378. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of New Mexico suffered actual damages and therefore is entitled to multiple damages under the New Mexico Medicaid False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT SEVENTY-TWO

VIOLATION OF THE NEW YORK FALSE CLAIMS ACT

N.Y. STATE FIN. LAW §189(1)(a)

379. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

380. This is a claim for penalties and treble damages under the New York False Claims Act.

381. As set forth above, from at least 2011 through the present, Defendants knowingly presented or caused to be presented to the State of New York false or fraudulent claims for payment or approval in violation of N.Y. State Fin. Law §189(1)(a).

382. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of New York suffered actual damages and therefore is entitled to multiple damages under the New York False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT SEVENTY-THREE

VIOLATION OF THE NEW YORK FALSE CLAIMS ACT

N.Y. STATE FIN. LAW §189(1)(b)

383. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

384. This is a claim for penalties and treble damages under the New York False Claims Act.

385. As set forth above, from at least 2011 through the present, Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim submitted to the State of New York in violation of N.Y. State Fin. Law §189(1)(b).

386. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of New York suffered actual damages and therefore is entitled to multiple damages under the New York False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT SEVENTY-FOUR

VIOLATION OF THE NEW YORK FALSE CLAIMS ACT

N.Y. STATE FIN. LAW §189(1)(c)

387. Relators incorporate by reference the allegations set forth in the foregoing

paragraphs as though fully set forth herein.

388. This is a claim for penalties and treble damages under the New York False Claims Act.

389. As set forth above, from at least 2011 through the present, Defendants knowingly conspired together to commit violations of the New York False Claims Act in violation of N.Y. State Fin. Law §189(1)(c).

390. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of New York suffered actual damages and therefore is entitled to multiple damages under the New York False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT SEVENTY-FIVE

VIOLATION OF THE NORTH CAROLINA FALSE CLAIMS ACT

N.C. GEN. STAT. §1-607(a)(1)

391. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

392. This is a claim for penalties and treble damages under the North Carolina False Claims Act.

393. As set forth above, from at least 2011 through the present, Defendants knowingly presented or caused to be presented to the State of North Carolina false or fraudulent claims for payment or approval in violation of N.C. Gen. Stat. §1-607(a)(1).

394. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of North Carolina suffered actual damages and therefore is entitled to multiple damages under the North Carolina False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT SEVENTY-SIX

VIOLATION OF THE NORTH CAROLINA FALSE CLAIMS ACT

N.C. GEN. STAT. §1-607(a)(2)

395. Relators incorporate by reference the allegations set forth in the foregoing

paragraphs as though fully set forth herein.

396. This is a claim for penalties and treble damages under the North Carolina False Claims Act.

397. As set forth above, from at least 2011 through the present, Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim submitted to the State of North Carolina in violation of N.C. Gen. Stat. §1-607(a)(1).

398. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of North Carolina suffered actual damages and therefore is entitled to multiple damages under the North Carolina False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT SEVENTY-SEVEN

VIOLATION OF THE NORTH CAROLINA FALSE CLAIMS ACT

N.C. GEN. STAT. §1-607(a)(3)

399. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

400. This is a claim for penalties and treble damages under the North Carolina False Claims Act.

401. As set forth above, from at least 2011 through the present, Defendants knowingly conspired together to commit violations of the North Carolina False Claims Act in violation of N.C. Gen. Stat. §1-607(a)(1).

402. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of North Carolina suffered actual damages and therefore is entitled to multiple damages under the North Carolina False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT SEVENTY-EIGHT

VIOLATION OF THE OKLAHOMA MEDICAID FALSE CLAIMS ACT

63 OKLA. STAT. §5053.1B(1)

403. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

404. This is a claim for penalties and treble damages under the Oklahoma Medicaid False Claims Act.

405. As set forth above, from at least 2011 through the present, Defendants knowingly presented or caused to be presented to the State of Oklahoma false or fraudulent claims for payment or approval in violation of 63 Okla. Stat. §5053.1B(1).

406. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Oklahoma suffered actual damages and therefore is entitled to multiple damages under the Oklahoma Medicaid False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT SEVENTY-NINE

VIOLATION OF THE OKLAHOMA MEDICAID FALSE CLAIMS ACT

63 OKLA. STAT. §5053.1B(2)

407. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

408. This is a claim for penalties and treble damages under the Oklahoma Medicaid False Claims Act.

409. As set forth above, from at least 2011 through the present, Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim submitted to the State of Oklahoma in violation of 63 Okla. Stat. §5053.1B(2).

410. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Oklahoma suffered actual damages and therefore is entitled to multiple damages under the Oklahoma Medicaid False Claims Act, to be determined at

trial, plus a civil penalty for each violation.

COUNT EIGHTY

VIOLATION OF THE OKLAHOMA MEDICAID FALSE CLAIMS ACT

63 OKLA. STAT. §5053.1B(3)

411. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

412. This is a claim for penalties and treble damages under the Oklahoma Medicaid False Claims Act.

413. As set forth above, from at least 2011 through the present, Defendants knowingly conspired together to commit violations of the Oklahoma Medicaid False Claims Act in violation of 63 Okla. Stat. §5053.1B(3).

414. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Oklahoma suffered actual damages and therefore is entitled to multiple damages under the Oklahoma Medicaid False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT EIGHTY-ONE

VIOLATION OF THE RHODE ISLAND FALSE CLAIMS ACT

R.I. GEN. LAWS §9-1.1-3(a)(1)

415. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

416. This is a claim for penalties and treble damages under the Rhode Island False Claims Act.

417. As set forth above, from at least 2011 through the present, Defendants knowingly presented or caused to be presented to the State of Rhode Island false or fraudulent claims for payment or approval in violation of R.I. Gen. Laws §9-1.1-3(a)(1).

418. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Rhode Island suffered actual damages and therefore is entitled to multiple damages under the Rhode Island False Claims Act, to be determined at trial,

plus a civil penalty for each violation.

COUNT EIGHTY-TWO

VIOLATION OF THE RHODE ISLAND FALSE CLAIMS ACT

R.I. GEN. LAWS §9-1.1-3(a)(2)

419. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

420. This is a claim for penalties and treble damages under the Rhode Island False Claims Act.

421. As set forth above, from at least 2011 through the present, Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim submitted to the State of Rhode Island in violation of R.I. Gen. Laws §9-1.1-3(a)(2).

422. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Rhode Island suffered actual damages and therefore is entitled to multiple damages under the Rhode Island False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT EIGHTY-THREE

VIOLATION OF THE RHODE ISLAND FALSE CLAIMS ACT

R.I. GEN. LAWS §9-1.1-3(a)(3)

423. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

424. This is a claim for penalties and treble damages under the Rhode Island False Claims Act.

425. As set forth above, from at least 2011 through the present, Defendants knowingly conspired together to commit violations of the Rhode Island False Claims Act in violation of R.I. Gen. Laws §9-1.1-3(a)(3).

426. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Rhode Island suffered actual damages and therefore is entitled

to multiple damages under the Rhode Island False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT EIGHTY-FOUR

VIOLATION OF THE TENNESSEE FALSE CLAIMS ACT

TENN. CODE ANN. §4-18-103(a)(1)

427. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

428. This is a claim for penalties and treble damages under the Tennessee False Claims Act.

429. As set forth above, from at least 2011 through the present, Defendants knowingly presented or caused to be presented to the State of Tennessee false or fraudulent claims for payment or approval in violation of Tenn. Code Ann. §4-18-103(a)(1).

430. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Tennessee suffered actual damages and therefore is entitled to multiple damages under the Tennessee False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT EIGHTY-FIVE

VIOLATION OF THE TENNESSEE FALSE CLAIMS ACT

TENN. CODE ANN. §4-18-103(a)(2)

431. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

432. This is a claim for penalties and treble damages under the Tennessee False Claims Act.

433. As set forth above, from at least 2011 through the present, Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim submitted to the State of Tennessee in violation of Tenn. Code Ann. §4-18-103(a)(2).

434. By virtue of the false or fraudulent claims submitted or caused to be submitted

by Defendants, the State of Tennessee suffered actual damages and therefore is entitled to multiple damages under the Tennessee False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT EIGHTY-SIX

VIOLATION OF THE TENNESSEE FALSE CLAIMS ACT

TENN. CODE ANN. §4-18-103(a)(3)

435. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

436. This is a claim for penalties and treble damages under the Tennessee False Claims Act.

437. As set forth above, from at least 2011 through the present, Defendants knowingly conspired together to commit violations of the Tennessee False Claims Act in violation of Tenn. Code Ann. §4-18-103(a)(3).

438. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Tennessee suffered actual damages and therefore is entitled to multiple damages under the Tennessee False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT EIGHTY-SEVEN

VIOLATION OF THE TENNESSEE MEDICAID FALSE CLAIMS ACT

TENN. CODE ANN. §71-5-182(a)(1)(A)

439. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

440. This is a claim for penalties and treble damages under the Tennessee Medicaid False Claims Act.

441. As set forth above, from at least 2011 through the present, Defendants knowingly presented or caused to be presented to the State of Tennessee false or fraudulent claims for payment or approval in violation of Tenn. Code Ann. §71-5-182(a)(1)(A).

442. By virtue of the false or fraudulent claims submitted or caused to be submitted

by Defendants, the State of Tennessee suffered actual damages and therefore is entitled to multiple damages under the Tennessee Medicaid False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT EIGHTY-EIGHT

VIOLATION OF THE TENNESSEE MEDICAID FALSE CLAIMS ACT

TENN. CODE ANN. §71-5-182(a)(1)(B)

443. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

444. This is a claim for penalties and treble damages under the Tennessee Medicaid False Claims Act.

445. As set forth above, from at least 2011 through the present, Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim submitted to the State of Tennessee in violation of Tenn. Code Ann. §71-5-182(a)(1)(B).

446. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Tennessee suffered actual damages and therefore is entitled to multiple damages under the Tennessee Medicaid False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT EIGHTY-NINE

VIOLATION OF THE TENNESSEE MEDICAID FALSE CLAIMS ACT

TENN. CODE ANN. §71-5-182(a)(1)(C)

447. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

448. This is a claim for penalties and treble damages under the Tennessee Medicaid False Claims Act.

449. As set forth above, from at least 2011 through the present, Defendants knowingly conspired together to commit violations of the Tennessee Medicaid False Claims Act in violation of Tenn. Code Ann. §71-5-182(a)(1)(C).

450. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Tennessee suffered actual damages and therefore is entitled to multiple damages under the Tennessee Medicaid False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT NINETY

VIOLATION OF THE TEXAS MEDICAID FRAUD PREVENTION LAW

TEX. HUM. RES. CODE §36.002(1)

451. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

452. This is a claim for penalties and treble damages under the Texas Medicaid Fraud Prevention Law.

453. As set forth above, from at least 2011 through the present, Defendants knowingly presented or caused to be presented to the State of Texas false or fraudulent claims for payment or approval in violation of Tex. Hum. Res. Code §36.002(1).

454. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Texas suffered actual damages and therefore is entitled to multiple damages under the Texas Medicaid Fraud Prevention Law, to be determined at trial, plus a civil penalty for each violation.

COUNT NINETY-ONE

VIOLATION OF THE TEXAS MEDICAID FRAUD PREVENTION LAW

TEX. HUM. RES. CODE §36.002(4)(A)

455. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

456. This is a claim for penalties and treble damages under the Texas Medicaid Fraud Prevention Law.

457. As set forth above, from at least 2011 through the present, Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim submitted to the State of Texas in violation of Tex. Hum.

Res. Code §36.002(4)(A).

458. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Texas suffered actual damages and therefore is entitled to multiple damages under the Texas Medicaid Fraud Prevention Law, to be determined at trial, plus a civil penalty for each violation.

COUNT NINETY-TWO

VIOLATION OF THE TEXAS MEDICAID FRAUD PREVENTION LAW

TEX. HUM. RES. CODE §36.002(9)

459. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

460. This is a claim for penalties and treble damages under the Texas Medicaid Fraud Prevention Law.

461. As set forth above, from at least 2011 through the present, Defendants knowingly conspired together to commit violations of the Texas Medicaid Fraud Prevention Law in violation of Tex. Hum. Res. Code §36.002(9).

462. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Texas suffered actual damages and therefore is entitled to multiple damages under the Texas Medicaid Fraud Prevention Law, to be determined at trial, plus a civil penalty for each violation.

COUNT NINETY-THREE

VIOLATION OF THE VERMONT FALSE CLAIMS ACT

32 VT. STAT. ANN. §631(a)(1)

463. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

464. This is a claim for penalties and treble damages under the Vermont False Claims Act.

465. As set forth above, from at least 2011 through the present, Defendants knowingly presented or caused to be presented to the State of Vermont false or fraudulent

claims for payment or approval in violation of Vt. Stat. Ann. §631(a)(1).

466. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Vermont suffered actual damages and therefore is entitled to multiple damages under the Vermont False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT NINETY-FOUR

VIOLATION OF THE VERMONT FALSE CLAIMS ACT

32 VT. STAT. ANN. §631(a)(2)

467. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

468. This is a claim for penalties and treble damages under the Vermont False Claims Act.

469. As set forth above, from at least 2011 through the present, Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim submitted to the State of Vermont in violation of Vt. Stat. Ann. §631(a)(2).

470. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Vermont suffered actual damages and therefore is entitled to multiple damages under the Vermont False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT NINETY-FIVE

VIOLATION OF THE VERMONT FALSE CLAIMS ACT

32 VT. STAT. ANN. §631(a)(12)

471. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

472. This is a claim for penalties and treble damages under the Vermont False Claims Act.

473. As set forth above, from at least 2011 through the present, Defendants

knowingly conspired together to commit violations of the Vermont False Claims Act in violation of Vt. Stat. Ann. §631(a)(12).

474. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Vermont suffered actual damages and therefore is entitled to multiple damages under the Vermont False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT NINETY-SIX

VIOLATION OF THE VIRGINIA FRAUD AGAINST TAXPAYERS ACT

VA. CODE ANN. §8.01-216.3(A)(1)

475. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

476. This is a claim for penalties and treble damages under the Virginia Fraud Against Taxpayers Act.

477. As set forth above, from at least 2011 through the present, Defendants knowingly presented or caused to be presented to the Commonwealth of Virginia false or fraudulent claims for payment or approval in violation of Va. Code Ann. §8.01-216.3(A)(1).

478. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the Commonwealth of Virginia suffered actual damages and therefore is entitled to multiple damages under the Virginia Fraud Against Taxpayers Act, to be determined at trial, plus a civil penalty for each violation.

COUNT NINETY-SEVEN

VIOLATION OF THE VIRGINIA FRAUD AGAINST TAXPAYERS ACT

VA. CODE ANN. §8.01-216.3(A)(2)

479. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

480. This is a claim for penalties and treble damages under the Virginia Fraud Against Taxpayers Act.

481. As set forth above, from at least 2011 through the present, Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim submitted to the Commonwealth of Virginia in violation of Va. Code Ann. §8.01-216.3(A)(2).

482. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the Commonwealth of Virginia suffered actual damages and therefore is entitled to multiple damages under the Virginia Fraud Against Taxpayers Act, to be determined at trial, plus a civil penalty for each violation.

COUNT NINETY-EIGHT

VIOLATION OF THE VIRGINIA FRAUD AGAINST TAXPAYERS ACT

VA. CODE ANN. §8.01-216.3(A)(3)

483. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

484. This is a claim for penalties and treble damages under the Virginia Fraud Against Taxpayers Act.

485. As set forth above, from at least 2011 through the present, Defendants knowingly conspired together to commit violations of the Virginia Fraud Against Taxpayers Act in violation of Va. Code Ann. §8.01-216.3(A)(3).

486. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the Commonwealth of Virginia suffered actual damages and therefore is entitled to multiple damages under the Virginia Fraud Against Taxpayers Act, to be determined at trial, plus a civil penalty for each violation.

COUNT NINETY-NINE

VIOLATION OF THE WASHINGTON STATE MEDICAID FRAUD FALSE CLAIMS ACT

WASH REV. CODE §74.66.020(1)(a)

487. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

488. This is a claim for penalties and treble damages under the Washington State Medicaid Fraud False Claims Act.

489. As set forth above, from at least 2011 through the present, Defendants knowingly presented or caused to be presented to the State of Washington false or fraudulent claims for payment or approval in violation of Wash. Rev. Code §74.66.020(1)(a).

490. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Washington suffered actual damages and therefore is entitled to multiple damages under the Washington State Medicaid Fraud False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT ONE-HUNDRED

VIOLATION OF THE WASHINGTON MEDICAID FALSE CLAIMS ACT

WASH. REV. CODE §74.66.020(1)(b)

491. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

492. This is a claim for penalties and treble damages under the Washington State Medicaid Fraud False Claims Act.

493. As set forth above, from at least 2011 through the present, Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim submitted to the State of Washington in violation of Wash. Rev. Code §74.66.020(1)(b).

494. By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Washington suffered actual damages and therefore is entitled to multiple damages under the Washington State Medicaid Fraud False Claims Act, to be determined at trial, plus a civil penalty for each violation.

COUNT ONE-HUNDRED-AND-ONE

VIOLATION OF THE WASHINGTON MEDICAID FALSE CLAIMS ACT

WASH. REV. CODE §74.66.020(1)(c)

495. Relators incorporate by reference the allegations set forth in the foregoing paragraphs as though fully set forth herein.

496. This is a claim for penalties and treble damages under the Washington State Medicaid Fraud False Claims Act.

497. As set forth above, from at least 2011 through the present, Defendants knowingly conspired together to commit violations of the Washington State Medicaid Fraud False Claims Act in violation of Wash. Rev. Code §74.66.020(1)(c).

By virtue of the false or fraudulent claims submitted or caused to be submitted by Defendants, the State of Washington suffered actual damages and therefore is entitled to multiple damages under the Washington State Medicaid Fraud False Claims Act, to be determined at trial, plus a civil penalty for each violation.

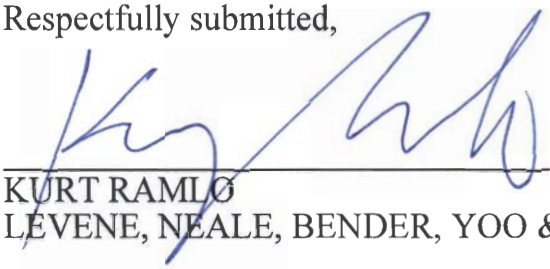
PRAYER FOR RELIEF

WHEREFORE, the United States and Relators demand that judgment be entered against Defendants and in favor of the Relator and the United States as follows:

On the first through one-hundred-and-first causes of action under the federal False Claims Act (and as amended and equivalent state statutes), a judgment for the amount of the United States' and the States' damages, multiplied by three as required by law, and such civil penalties as are permitted or required by law; the maximum share amount allowed pursuant to 31 U.S.C. § 3730(d) and applicable State laws; all costs and expenses of this action, including attorney fees, expenses and costs as permitted by 31 U.S.C. § 3730(d) and applicable State laws; and all such other relief as may be just and proper.

Dated: November 13, 2018

Respectfully submitted,



KURT RAMLO
LEVENE, NEALE, BENDER, YOO & BRILL L.L.P.

- and -

Gregory M. Utter * (OH Bar No. 0032528)
Joseph M. Callow, Jr. * (OH Bar No. 0061814)
KEATING MUETHING & KLEKAMP PLL

- and -

Joel D. Hesch * (DC Bar No. 421822)
THE HESCH FIRM, LLC

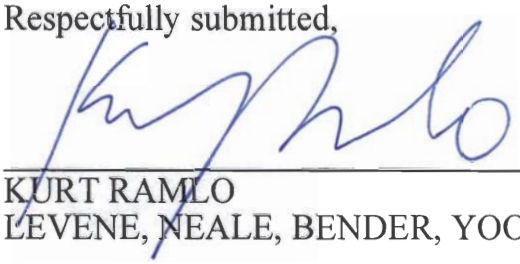
ATTORNEYS FOR RELATORS
** Pro hac vice applications forthcoming*

REQUEST FOR TRIAL BY JURY

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Relators hereby demand a trial by jury.

Dated: November 13, 2018

Respectfully submitted,



KURT RAMLO
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- and -

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THE HESCH FIRM, LLC

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** Pro hac vice applications forthcoming*

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EXHIBIT A

NIHON KOHDEN

EQUIPMENT DIMENSIONS, WEIGHT, POWER SPECIFICATIONS

BEDSIDE MONITORS						
Product:	Power Watts	Width Inches	Height Inches	Depth Inches	Weight Pounds	BTU/hr
OPV-1500K	70	7.7	8.1	7.3	10 *	239
BSM-1700 series monitor	40 on battery	5.8	7.6	3.7	3 *	59
BSM-1700 docking base	80 monitor and base	7.4	2.9	4.9	2	89
BSM-2350 series	70	11.5	10.8	5.7	11 *	239
BSM-2350 series w/ recorder	70	11.5	12.8	5.7	15 *	239
BSM-4100 series	80	13.4	14.8	6.3	21 *	273
BSM-5105/5106	130	13.4	12.4	10	19 *	444
BSM-5135/5136	130	13.4	12.4	10	23 *	444
BMS-6300 series	140	12.5	12.8	7.4	16.9 *	478
BSM-6500 series	90	13.5	13.9	7.2	20.6 *	307
BSM-6700 series	100	16.4	15.5	7.6	25 *	341
BSM-9100 series						
Main unit	210	3.4	10.7	13.4	17.4*	717
Display	65	16.2	12.1	2.4	9.5*	222
Interface		3.2	2.9	6.7	1.6*	

* Excluding Options

CENTRAL STATION MONITORS						
Product:	Power Watts	Width Inches	Height Inches	Depth Inches	Weight Pounds	BTU/hr
Prefense:						
Main Unit	90	6.5	6.3	1.9	2.4	308
LCD unit	195	25.4	20.1	9.6	21.6	665
CNS-6201:						
Main Unit	180	4.6	13.8	15	24.2	615
Display (LCD unit)	185	23.4	15.7	2.8	24.2	632
CNS-9701A:						
Main Unit	230	7.0	13.9	16	35	785
Display	150	18.0	18.6	9.8	24	512
Recorder	100	3.7	7	8.2	5	341
RNS-9703						
19”	45	16.2	15.2	7.8	14.2	154

NIHON KOHDEN

EQUIPMENT DIMENSIONS, WEIGHT, POWER SPECIFICATIONS

24”	65	23.6	15.2	8.9	19.5	222
UPS ABCE600-11/ 54060-03R*	5.0/3.5 amps	5.8	8.0	17.5	41	108
WEP-4208A	80	13.4	14.8	6.3	20	273

TELEMETRY RECEIVER & ANTENNA						
Product:	Power Watts	Width Inches	Height Inches	Depth Inches	Weight Pounds	BTU/hr
ORG-9100A	25	9.8	2.9	8.9	8	86
ORG-9700A	60	6.2	8.0	12	13.5	205
PS-3015 Power Supply (2 required)	180	9	2 .3	5	3	615
UPS ABCE600-11 / 54060-03R*	5.0/3.5 amps	5.8	8.0	17.5	41	108

NETWORKING EQUIPMENT						
Product:	Power Watts	Width Inches	Height Inches	Depth Inches	Weight Pounds	BTU/hr
Cisco Catalyst 3650 Series Switch	1025	17.5	1.73	17.625	15.15	3497
Cisco 300 Series Switch	155	11	1.45	6.7	4.78	527
SMC GS Series Switch	525	17.3	1.7	13.8	6.6	TBD

LASER PRINTER						
Product:	Power Watts (Printing)	Width Inches	Height Inches	Depth Inches	Weight Pounds	BTU/hr
HP LaserJet 600 (M602n)	820	16.3	20	15.7	52	2798

SERVER PRODUCTS						
Product:	Power Watts	Width Inches	Height Inches	Depth Inches	Weight Pounds	BTU/hr
HL7 (PowerEdge R220)	345	17.6	1.68	21.5	26	1178
NetKonnect (PowerEdge R220)						
ECG Gateway (PowerEdge R220)						
CGS Gateway (PowerEdge R220)						

Power requirements, All Equipment:

AC	AC 117 V ±10%
Line frequency	60 Hz ±2%

Operating Environment, All Equipment:

Temperature	10 to 35^{O} C
Humidity	30 to 85% RH (0 to 40 ^{O} C, non-condensing)
Atmospheric pressure	70 to 106 kPa

EXHIBIT B

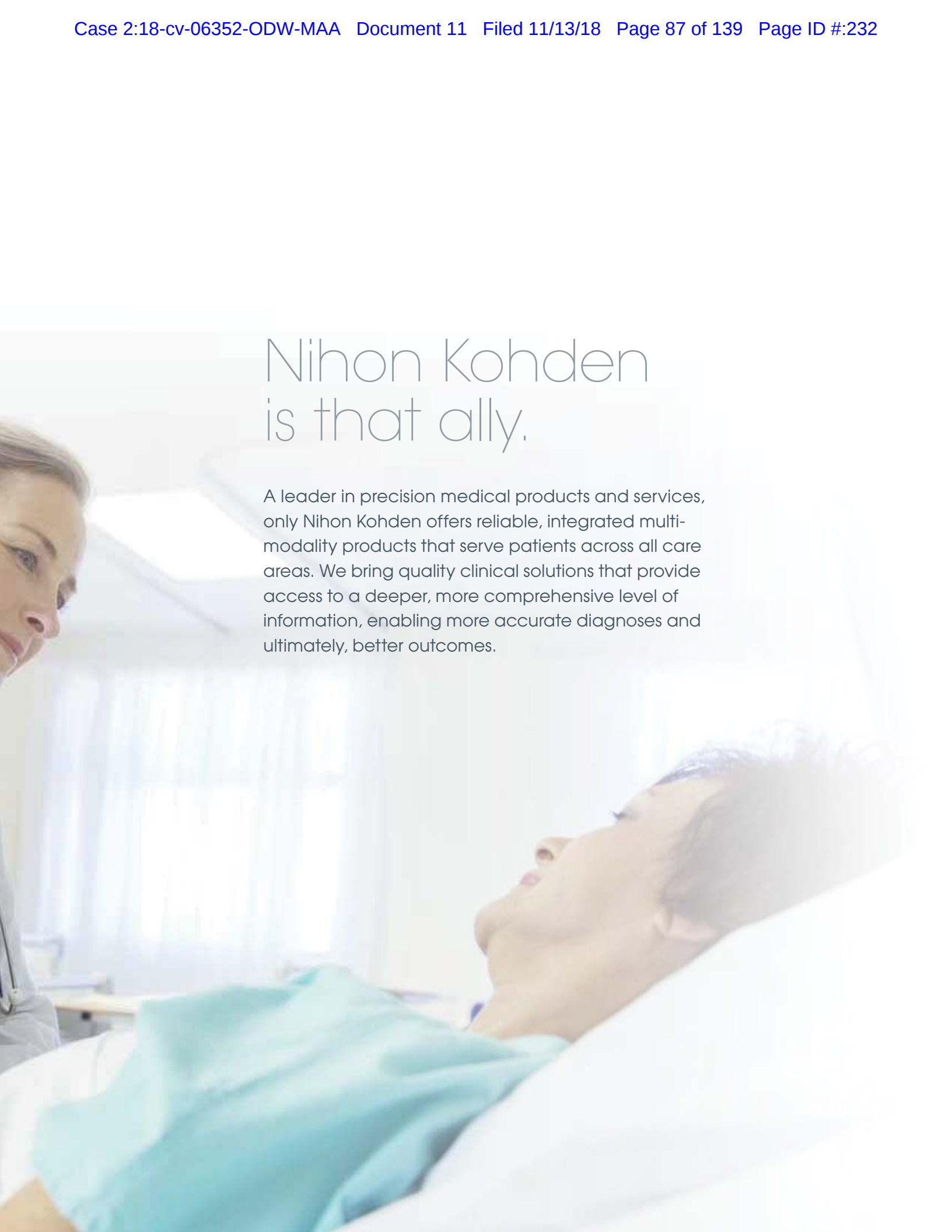
One Standard Across the Care Continuum

BSM-6000 series bedside monitors

NIHON KOHDEN

Breaking Down Barriers to Care

The Institute of Healthcare Improvement's triple aim—designed to push quality initiatives while simultaneously fostering marketplace efficiencies—has rippled across the healthcare continuum. Advancement simply for the sake of change is not enough; it must enhance healthcare in some way. Improvements must be quantifiable, as well as qualifiable. Care must be coordinated. Every clinician must manage greater risk as patients present with multiple comorbidities. To navigate this dynamic, providers across the spectrum—from the smallest practices to the largest health systems—need allies capable of helping them remain ahead of the rapidly shifting environment while ensuring the highest quality of care for patients.



Nihon Kohden is that ally.

A leader in precision medical products and services, only Nihon Kohden offers reliable, integrated multi-modality products that serve patients across all care areas. We bring quality clinical solutions that provide access to a deeper, more comprehensive level of information, enabling more accurate diagnoses and ultimately, better outcomes.

Premium-as-Standard Design

We belive every patient deserves the highest standard of care. Nihon Kohden's premium-as-standard philosophy is the belief that every monitor should be fully appointed with features—both standard and premium—unlocked and ready to use at a moment's notice. This ensures that our technology can be employed in the broadest range of acuity levels and seamlessly transition between care areas as patient need dictates.

The BSM-6000 series of monitors offer unrivaled technology that works across the healthcare continuum and realizes our premium-as-standard philosophy, allowing providers to deliver care without compromise.

Some of our premium-as-standard capabilities include:

- Comprehensive arrhythmia detection and recall, including advanced Atrial Fibrillation algorithm
- Multi-waveform/multi-parameter full disclosure
- ST segment analysis as well as diagnostic 12 lead ECG capability
- Drug, hemodynamic and pulmonary calculations

BSM-6301
10.4-inch LCD

BSM-650
12.1-inch LC

Nihon Kohden's unique Smart Cable™ technology miniaturizes circuits found in traditional modules and embeds that circuitry into a Smart Patient Cable. When you plug a Smart Cable into a Multiport, the associated parameter is automatically detected, displayed and measured. With this technology, you'll get parameter flexibility at a significantly reduced cost with seamless and immediate access to blood pressure, cardiac output, $EtCO_2$, temperature, BIS, EEG and more, when and where you need it for rapid clinical assessment across care areas.

01
CD

BSM-6701
15-inch LCD

Arrhythmia

The BSM-6000 Series provides high accuracy multi-lead arrhythmia detection and storage of over 16,000 arrhythmia events. Each event is time-linked to the full disclosure waveforms to determine what led up to, and what followed, the captured event.

Full Disclosure

Full disclosure waveforms allow you to validate alarm and numeric findings and to make treatment decisions based on more accurate monitored data. The BSM-6000 Series provides storage and review capabilities at the bedside monitor that are typically found only in a central station.

ST Template

Multi-lead ST segment monitoring provides you with continuous oversight to transient changes in your patients' cardiac condition and are stored minute-to-minute in the monitor for comparison.

Redefining Transport

Continuity of monitored care during transport ensures the highest quality of care for patients. The unique design of Nihon Kohden's BSM-1700 Transport monitor and the BSM-6000 redefines transport monitoring. Simply disconnect the BSM-1700 Transport monitor from the BSM-6000 monitor or Data Acquisition Unit and your patient can be transported with all monitoring capabilities remaining the same. When the patient is transferred to their new care setting and the BSM-1700 is reconnected to another BSM-6000 or Life Scope G9 monitor and patient information, including full disclosure, is uploaded to the new bedside display creating one seamless, reliable patient record enhancing workflow and care coordination. Patient transport using the wireless option for the BSM-1700 provides uninterrupted Central Station Monitoring and WLAN Transport that manages your patient data automatically.

One additional benefit of the Data Acquisition Unit is that it can be extended via an umbilical cord to be located on a bed rail, gurney or IV pole next to the patient. This alleviates the hassles associated with cable management at the bedside. Since the Data Acquisition Unit contains user function keys, it can be placed on either side of the patient for optimal clinical workflow efficiency.

NIHON KOHDEN

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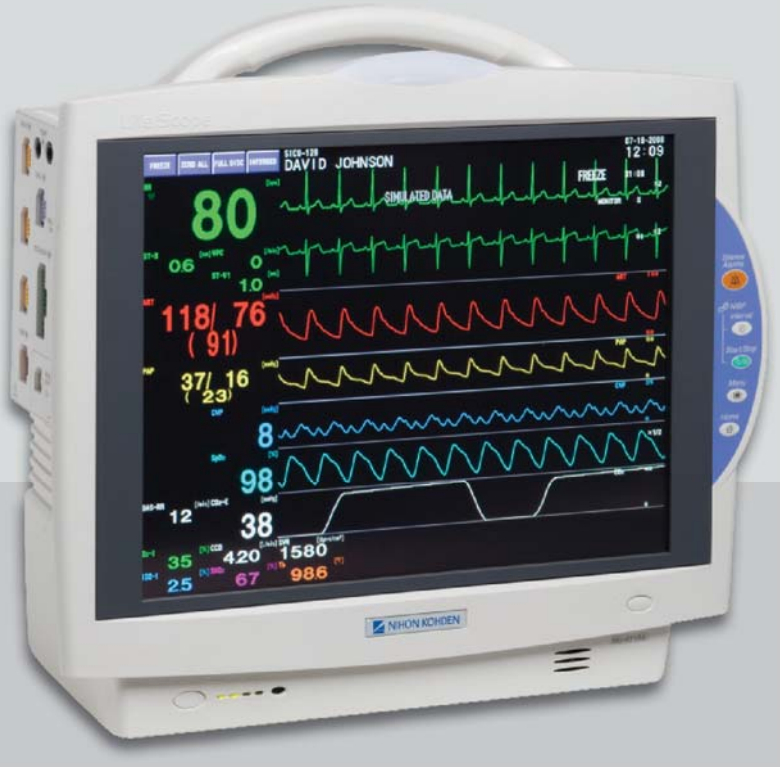
Different Thinking for Better Healthcare.®

MMLB 011 (C)-CO-1072

EXHIBIT C

Bedside Monitor
BSM-6701



One Standard Across the Care Continuum

- Premium-as-Standard Design:
  - Comprehensive arrhythmia detection and recall
  - Advanced Atrial Fibrillation algorithm
  - Multi-waveform, multi-parameter full disclosure
  - ST analysis and recall
  - Diagnostic 12-lead ECG
  - Drug, hemodynamic and pulmonary calculations
- Selection of input and expansion units provide flexible monitoring
- Continuity of monitored care during transport with BSM-1700 transport monitor
- 15″ high resolution touchscreen display for ease of operation

Specifications

Bedside Monitor BSM-6701

BSM-6701

DISPLAY

Display Size: 15" color TFT type LCD

Display Characteristics: Resolution: 1024 x 768. Touch screen with six quick access hard keys.

Maximum Number of Waveform Traces: Up to 15 traces

Display Waveforms: ECG (up to 12), respiration, IBP (up to 2), SpO_2 pulse wave, CO_2, BIS EEG (up to 2 traces), vent PAW, vent Flow, and CO Thermodilution curve. When gas is monitored: O_2 concentration curve, CO_2 concentration curve, anesthetic agent concentration (Halothane, Isoflurane, Enflurane, Sevoflurane, Desflurane) Analog input

Numerical Data Display: Heart rate, VPC rate, ST level, RR respiration rate, NIBP (systolic, diastolic, mean), IBP (systolic, diastolic, mean), SpO_2, SpO_2-2, delta SpO_2, pulse rate, temperature, CO, CI, Ti (injectate temperature), Tb (blood temperature), O_2 concentration, $EtCO_2$, BIS, inspired/ expired N_2O concentration, inspired/ expired CO_2, inspired/ expired O_2 concentration, inspired/ expired anesthetic agent concentration (Halothane, Isoflurane, Enflurane, Sevoflurane, Desflurane), MAC (minimum alveolar concentration), Ppeak (peak airway pressure), PEEP (positive end expiratory pressure), Pmean (mean airway pressure), MV (minute volume), TVi (inspiratory tidal volume), TVe (expiratory tidal volume), C (compliance), R (airway resistance), Ri (inspiratory airway resistance), Re (expiratory airway resistance), I:E (inspiration expiration ratio), SEF (90 or 95% spectral edge frequency), MDF (median frequency), PPF (peak power frequency), TP (total power), TP power of frequency, TOF, CCO, SVRI, SvO_2, EF, $ScvO_2$, CCI, EDV, SVR, EDVI, PCCO, PCCI, $tcPO_2$, $tcPCO_2$, PPV, SPV

ALARMS

Alarm Items: Vital sign alarms, arrhythmia alarms, technical alarms and operational alarms

Alarm Levels: Crisis (red blinking), Warning (yellow blinking), Advisory (yellow or blue light)

Alarm Indication: Alarm indicator (360° visibility) highlighted message, alarm sound

Alarm Suspend: 1, 2, or 3 min

PARAMETERS

ECG:
Number of ECG waveforms channels: Up to 12
Frequency response:
- Diagnosis mode: 0.05 to 150 Hz
- Monitor mode: 0.3 to 40 Hz
- Maximum filter mode: 1 to 18 Hz

Heart Rate Counting range: 0, 15 to 300 beats/min
Arrhythmia Analysis method: Multi-template software algorithm
VPC counting rate: 0 to 99 VPCs/min
Arrhythmia alarms: ASYSTOLE, VF, VT, V RHYTHM, V BRADY, EXT TACHY, EXT BRADY, AF, VPC RUN, COUPLET, EARLY VPC, BIGEMINY, TRIGEMINY, FREQ VPC, PROLONGED RR, SV TACHY, TACHYCARDIA, BRADYCARDIA, VPC, MULTIFORM, IRREGULAR RR, NO PACER PULSE, PACER NON-CAPTURE, PAUSE

ST Level Measurement: Number of measurement channels: Up to 12
Measuring range: ±2.5 mV

Respiration (Impedance or Thermistor Method): Measuring range: 0 to 150 breaths/min

SpO_2: Measuring Technology: Nihon Kohden, Massimo or Nellcor
Measuring Display Range: 0 to 100% (70 to 100% at specified accuracy)
Pulse rate from SpO_2 Range: 0, 30 to 300 beats/min (varies by SpO_2 technology)

Non Invasive Blood Pressure, NIBP: Measuring method: Oscillometric Cuff
Pressure display range: 0 to 300 mmHg

Invasive Blood Pressure, IBP: Measuring range: –50 to 300 mmHg
Pulse rate display range from IBP range: 30 to 300 beats/min

Temperature: Measuring range: 0 to 45°C
Number of channels: 4 maximum

Cardiac Output: Measuring method: Thermodilution method
Measuring range: Injectate temperature (Ti): 0°C to 27°C
Blood temperature (Tb): 15°C to 45°C
Thermodilution curve (delta Tb): 0°C to 2.5°C
Cardiac output (CO): 0.5 to 20 L/min

Inspired Oxygen Fractional Concentration: Measuring range: 0 to 100%

CO_2: CO_2 measuring range: 0 to 150 mmHg
Respiration rate counting range: 3 to 150 breaths/min

BIS: Input channels: 2
Measuring parameters: Bispectral Index (BIS), 95% Spectral Edge Frequency (SEF90, SEF95), Suppression Ratio (SR), EMG, Signal Quality Index (SQI)

STORED PATIENT DATA

Trendgraph: Trend parameters: All monitored parameters
Trend display time: Up to 72 hours

Vital Signs List: All monitored parameters for up to 72 hours.
Periodic: 4320 (1 per minute for 72 hours)

NIBP: Number of entries: 1,024 files

HEMO List: Number of entries: 1,024 files

Full Disclosure: Storage time: Up to 72 hours
Number of Waveforms stored: 5 maximum

ST Recall: Number of files: 4,320 files (1 per minute for 72 hours) for all monitoring leads

Alarm History: Number of entries: 16,384 files

Arrhythmia Recall: Number of files: 16,384 files

12-Lead Interpretive Recall: Number of files: 18 files

OCRG: Storage capacity: 72 hours

Hemodynamics Trend Table: Number of entries: 1,024 files

RECORDER (option)

Recording Method: Thermal array recording

Number of Channels: 3 traces (maximum)

POWER REQUIREMENT

AC: 100 to 240 V ±10%

DC (SB-671P): 8.5 to 12.6 V

Line Frequency: 50 or 60 Hz

Battery Operation time: 60 minutes

Power Input: AC 100 VA

DIMENSIONS AND WEIGHT

Dimensions: 16.4" x 15.4" x 7.5" (415 W x 392 H x 191 D mm)

Weight: 22.7 lbs (10.0 kg)

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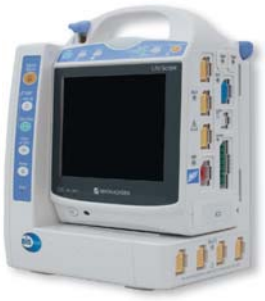
MMLB 052 [D]-CO-0884

EXHIBIT D

Transport Monitor
BSM-1700

One Standard of Care Across the Continuum of Care



- Functions as a compact stand-alone monitor, transport monitor or as an Input Unit for a BSM-6000, BSM-9000 or Life Scope G9 series bedside monitor
- Allows seamless transfer of data between bedside monitors and central stations
- 5 hour battery life
- Lightweight at only 3.4 lbs
- High-resolution touch screen display
- Comprehensive data storage:
    - Up to 72 hours full disclosure waveforms
    - Tabular & graphical trends
    - Arrhythmia recall files
    - ST recall files

Specifications

Transport Monitor
BSM-1700

BSM-1700

DISPLAY

Display Size: 5.7" Touch Screen Display

Display Modes: Standard, Transport

Maximum Number of Waveform Traces: 9 traces

Display Waveforms: ECG (up to 12 leads), respiration, IBP (up to 3 traces), SpO_2 pulse wave, CO_2, CO thermodilution Curve, BIS

Numerical Data Display: Heart rate, VPC rate, ST level, respiration rate, SpO_2, pulse rate, temperature, NIBP (systolic, diastolic, MAP), IBP (systolic, diastolic, mean), $EtCO_2$, $FiCO_2$, cardiac output, cardiac index, injectate temperature, blood temperature, BIS, SEF95, SR, EMG, SQI

ALARMS

Alarm Items: Upper/lower limits alarm, arrhythmia alarm

Alarm Levels: Crisis (red blinking), Warning (yellow blinking), Advisory (yellow or blue light)

Alarm Indication: Alarm indicator, highlighted message, alarm sound

Alarm Suspend: 1, 2, or 3 min or off

PARAMETERS

ECG:
Number of electrodes: 3, 6 or 10
Frequency response:
Diagnosis mode: 0.05 to 150 Hz
Monitor mode: 0.3 to 40 Hz
Maximum filter mode: 1 to 18 Hz
Heart Rate Counting range: 0, 15 to 300 beats/min
Arrhythmia analysis method: Multi-template matching software algorithm
VPC counting rate: 0 to 99 VPCs/min
Arrhythmia alarms: ASYSTOLE, VF, VT, V BRADY, EXT TACHY, EXT BRADY, SV TACHY, VPC RUN, TACHYCARDIA, BRADYCARDIA, COUPLET, EARLY VPC, MULTIFORM, V RHYTHM, PAUSE, BIGEMINY, TRIGEMINY, VPC, IRREGULAR RR, PACER NON-CAPTURE, PROLONGED RR, NO PACER PULSE, (NOISE, CHECK ELECTRODES, LEARNING)

ST Level Measurement: Number of measurement channels: Up to 12
Measuring range: ±2.5 mV

Respiration (Impedance Pneumography): Measuring range: 0 to 150 breaths/min

SpO_2:
Measuring Technology: Nihon Kohden, Massimo or Nellcor
Measuring Display Range: 0 to 100% (70 to 100% at specified accuracy)
Pulse rate from SpO_2 Range: 25 to 300 beats/min (varies by SpO_2 technology)

Non Invasive Blood Pressure, NIBP:
Measuring method: Oscillometric Cuff
Pressure display range: 0 to 300 mmHg

Invasive Blood Pressure, IBP:
Number of channels: Up to 3
Measuring range: –50 to 300 mmHg
Pulse rate from IBP range: 0, 30 to 300 beats/min

Temperature:
Measuring range: 0 to 45°C
Number of channels: 2 maximum

Cardiac Output:
Measuring method: Thermodilution method
Measuring range: Injectate temperature (Ti): 0°C to 27°C
Blood temperature (Tb): 15°C to 45°C
Thermodilution curve (delta Tb): 0°C to 2.5°C
Cardiac output (CO): 0.5 to 20 L/min

BIS:
Input channels: 1 or 2 (depends on the BIS sensor type)
Measuring parameters: Bispectral Index(BIS), 95% Spectral Edge Frequency (SEF95),Suppression Ratio (SR), EMG, Signal Quality Index (SQI)

CO_2:
CO_2 measuring range: 0 to 100 mmHg
Respiration rate counting range: 3 to 150 breaths min

STORED PATIENT DATA

Trendgraph:
Trend parameters: All monitored parameters
Trend display time: Up to 72 hours

Vital Signs List:
Trend parameters: All monitored parameters
Data Storage: Periodic: 4320 (1 per minute for 72 hours)

NIBP: 2,048 files

Full Disclosure:
Storage time: Up to 72 hours
Number of Waveforms stored: 5 maximum

Alarm History: Number of entries: 32,768 files

Hemodynamics Trend Table: Number of entries: 2,048 files

Arrhythmia Recall: Number of files: 32,768 files

ST Recall: Number of files: 4,320 files (1 per minute for 72 hours) for all monitoring leads

12 Lead Interpretive Recall: Number of files: 18 files

POWER REQUIREMENT

DC (SB-170P Lithium Ion Battery Pack): 9.0 to 12.6 V

Battery operation time: 5 hours

With SC-170R Cradle: Line voltage AC 100V to 240V

Line Frequency: 50 or 60 Hz

Power Input: 80 VA

DIMENSIONS AND WEIGHT

Dimensions: 147W× 194H × 94D mm

Weight: 1.57 kg with battery pack

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EXHIBIT E

Bedside Monitor Specification Comparison

	Accute Care/Hospital Market					ASC Market ONLY
	G9	**TR6000**	**TR6000**	**TR6000**	**TPM**	**TR3000**
	CSM-1901	**BSM-6700**	**BSM-6500**	**BSM-6300**	**BSM-1700**	**BSM-3500**
						
	Display					**Display**
Type	Color LCD	Color LCD	Color LCD	Color LCD	Color LCD	Color LCD
	21.5"	15"	12.1"	10.4"	5.7"	12"
Resolution	1920 x 1080	1024 x 768	800 x 600	800 x 600	640 x 480	800 x 600
Number Of Traces	17	15	15	15	9 (12 for ECG)	14
Touchscreen Operation	Yes	Yes	Yes	Yes	Yes	Yes
User Programmable Multi-Function Keys	Yes, 20	Yes, 4	Yes, 4	Yes, 4	Yes, 2	Yes, 4
Remote Control	Yes, Optional	Yes, Optional	Yes, Optional	Yes, Optional	N/A	Yes, Optional
	Parameters					**Parameters**
ECG Leads on Main Screen	Up to 12	Up to 3	Up to 3	Up to 3	Up to 3	Up to 3
Number of Viewable ECG Leads (any screen)	12	12	12	12	12	12
Number Of ECG Electrodes	3, 6 or 10	3, 6 or 10	3, 6 or 10	3, 6 or 10	3, 6 or 10	3, 6, or 10
SpO_2, NIBP	Yes (Configured)	Yes (Configured)	Yes (Configured)	Yes (Configured)	Yes (Configured)	Yes (Configured)

	G9	TR6000	TR6000	TR6000	TPM	TR3000
	CSM-1901	BSM-6700	BSM-6500	BSM-6300	BSM-1700	BSM-3500
	Parameters					**Parameters**
IBP, CO_2, Cardiac Output	Yes (Smart Modular Cable)	Yes (Smart Modular Cable)	Yes (Smart Modular Cable)	Yes (Smart Modular Cable)	Yes (Smart Modular Cable)	Yes (Smart Modular Cable)
FiO_2, Thermistor Respiration	Yes (Smart Modular Cable)	Yes (Smart Modular Cable)	Yes (Smart Modular Cable)	Yes (Smart Modular Cable)	Yes (Smart Modular Cable)	Yes (Smart Modular Cable)
Temperature	Yes 2 Configured 2 Smart Cable	Yes 2 Configured 2 Smart Cable	Yes 2 Configured 2 Smart Cable	Yes 2 Configured 2 Smart Cable	Yes 2 Configured	Yes 2 Configured 2 Smart Cable
BIS	Yes (Smart Modular Cable, or External Device)	Yes (Smart Modular Cable, or External Device)	Yes (Smart Modular Cable, or External Device)	Yes (Smart Modular Cable, or External Device)	Yes (Smart Modular Cable)	Yes (Smart Modular Cable, or External Device)
	Multi-Connectors					**Multi-Connectors**
Number of Multi-Connectors	7 Options to Expand to 11	3 or 7 Depending upon Model	3 or 7 Depending upon Model	1, 3 or 7 Depending upon Model	3	2
	Recorder					**Recorder**
3 Channel	Yes, Optional	Yes, Optional	Yes, Optional	Yes, Optional	No	Yes, Optional
	Battery Operation					**Battery Operation**
Standard or Optional	Standard	Standard	Standard	Optional	Optional	Optional
Operation Time	1 battery = 3 min	2 batteries = 2 hrs	2 batteries = 3 hrs	2 batteries = 3 hrs	5 hrs	1 battery = 1.5 hrs

	G9	TR6000	TR6000	TR6000	TPM	TR3000
	CSM-1901	BSM-6700	BSM-6500	BSM-6300	BSM-1700	BSM-3500
	Monitor Functions					Monitor Functions
Full Disclosure	5 Waves for 168 Hours, 8 Waves for 96 Hours, 35 Waves for 24 Hours	5 Waves 72 Hours Standard (24 Hours if X-Port Data is on)	5 Waves 72 Hours Standard (24 Hours if X-Port Data is on)	5 Waves 72 Hours Standard (24 Hours if X-Port Data is on)	5 Waves 72 Hours Standard (24 Hours if X-Port Data is on)	5 Waves 72 Hours Standard
Graphical Trends	168 Hours	72 Hours	72 Hours	72 Hours	72 Hours	72 Hours
Tabular Trends	168 Hours for up to 108 Parameters	4,320 Files (72 Hours, 24 Hours if X-Port Data is On)	4,320 Files (72 Hours, 24 Hours if X-Port Data is On)	4,320 Files (72 Hours, 24 Hours if X-Port Data is On)	4,320 Files (72 Hours, 24 Hours if X-Port Data is On)	4,320 Files (72 Hours)
NIBP Tabular Trends	1,008 Files (168 Hours)	1,024 Files (72 hours, 24 hours if X-Port Data is on)	1,024 Files (72 hours, 24 hours if X-Port Data is on)	1,024 Files (72 hours, 24 hours if X-Port Data is on)	1,024 Files (72 Hours, 24 Hours if X-Port Data is on)	1,024 Files (72 Hours)
Arrhythmia Recall	60,480 Files (168 Hours)	16,348 Files (72 Hours)	16,348 Files (72 Hours)	16,348 Files (72 Hours)	24,576 Files (72 Hours)	16,348 Files (72 Hours)
Alarm History	302,400 Files for the Past (168 Hours)	16,348 Files (72 Hours)	16,348 Files (72 Hours)	16,348 Files (72 Hours)	16,348 Files (72 Hours)	16,348 Files (72 Hours)
ST Recall	10,080 Files	4,320 Files, 12 Leads, Standard (72 Hours, 24 Hours if X-Port Data is On)	4,320 Files, 12 Leads, Standard (72 Hours, 24 Hours if X-Port Data is On)	4,320 Files, 12 Leads, Standard (72 Hours, 24 Hours if X-Port Data is On)	4,320 Files, 12 Leads, Standard (72 Hours, 24 Hours if X-Port Data is On)	4,320 Files, 12 Leads, Standard

	G9	TR6000	TR6000	TR6000	TPM	TR3000
	CSM-1901	BSM-6700	BSM-6500	BSM-6300	BSM-1700	BSM-3500
	Monitor Functions					Monitor Functions
Drug Calculations	Yes	Yes	Yes	Yes	N/A	Yes
Interpretive 12 Lead ECG Storage	672 Files (72 Hours)	18 Files (72 Hours)	18 Files (72 Hours)	18 Files (72 Hours)	18 Files (72 Hours)	18 Files (72 Hours)
Hemodynamic Calculations	1,008 Files	1,024 Files	1,024 Files	1,024 Files	1,536 Files	1,024 Files
Pulmonary Calculations	1,008 Files	512 Files (72 Hours)	512 Files (72 Hours)	512 Files (72 Hours)	N/A	512 Files (72 Hours)
Interbed Display	Yes, with 16 Bed Views	Yes, with 16 Bed Views	Yes, with 16 Bed Views	Yes, with 16 Bed Views	Yes, with 9 Bed Views	Yes, with 20 Dual Bed Views
MAC Display (minimum alveolar concentration)	Yes	Yes	Yes	Yes	N/A	Yes
Data Transport with Upload to CNS	Yes	Yes	Yes	Yes	Yes	No
	ECG					ECG
Multi-Lead Arrhythmia Processing	Yes, Dual Lead	Yes, Dual Lead	Yes, Dual Lead	Yes, Dual Lead	Yes, Dual Lead	Yes, Dual Lead
Interpretive 12-Lead ECG	Yes	Yes	Yes	Yes	Yes	Yes

	G9	TR6000	TR6000	TR6000	TPM	TR3000
	CSM-1901	BSM-6700	BSM-6500	BSM-6300	BSM-1700	BSM-3500
	SpO2					**SpO2**
SpO2 Technology	Nellcor OxyMax, Masimo SET or Nihon Kohden SpO2	Nellcor OxyMax, Masimo SET or Nihon Kohden SpO2	Nellcor OxyMax, Masimo SET or Nihon Kohden SpO2	Nellcor OxyMax, Masimo SET or Nihon Kohden SpO2	Nellcor OxyMax, Masimo SET or Nihon Kohden SpO2	Nellcor OxyMax, Masimo SET or Nihon Kohden SpO2
	NIBP					**NIBP**
Method	Oscillometric	Oscillometric	Oscillometric	Oscillometric	Oscillometric	Oscillometric
Special NIBP Modes	Staged Interval and Venous Puncture	Staged Interval and Venous Puncture	Staged Interval and Venous Puncture	Staged Interval and Venous Puncture	Staged Interval and Venous Puncture	Staged Interval and Venous Puncture
	Invasive Pressure (IBP)					**Invasive Pressure (IBP)**
Number of Channels	Up to 8 Depending on Number of Multiport Connectors	Up to 7 Depending on Number of Multiport Connectors	Up to 7 Depending on Number of Multiport Connectors	Up to 7 Depending on Number of Multiport Connectors	Up to 3	Up to 2
CPP Display (Cerebral Perfusion Pressure for ICP)	Yes	Yes	Yes	Yes	No	Yes
	Communications					**Communications**
Hardwired Central Communications	Yes	Yes	Yes	Yes	Yes, when using SC-170R Docking Station	Yes

	G9	TR6000	TR6000	TR6000	TPM	TR3000
	CSM-1901	BSM-6700	BSM-6500	BSM-6300	BSM-1700	BSM-3500
	Communications					Communications
W-LAN (Wireless) Central Communications	N/A	Optional, Requires QI-420-PA	Optional, Requires QI-420-PA	Optional, Requires QI-420-PA	Yes (QI-170P)	Optional, Requires QI-420-PA
ECG Output	Yes	Yes	Yes	Yes	Yes	Yes
IBP Output	Yes	Yes	Yes	Yes	Yes	Yes
External monitor output	Yes, Using Data Export Cable YS-094P2	Optional, Requires QI-671P and Standard Video Cable	Optional, Requires QI-671P and Standard Video Cable	Optional, Requires QI-671P and Standard Video Cable	No	Optional, Requires QI-372P
Laser Printer Documentation without Central	Yes	Yes	Yes	Yes	Yes, when using SC-170R Docking Station or WLAN	Yes
Laser Printer Documentation with Central	Yes	Yes	Yes	Yes	Yes, when using SC-170R Docking Station or WLAN	Yes
USB Interface to External Devices	Yes	Optional, Requires QI-672P. Supports USB Mouse or Bar Code Scanner.	Optional, Requires QI-672P. Supports USB Mouse or Bar Code Scanner.	Optional, Requires QI-672P. Supports USB Mouse or Bar Code Scanner.	No	Optional with QI Equipped Models. No USB.

	G9	TR6000	TR6000	TR6000	TPM	TR3000
	CSM-1901	BSM-6700	BSM-6500	BSM-6300	BSM-1700	BSM-3500
	External Device Interfaces					External Device Interfaces
Maximum Number of External Devices	3 Standard on G9 CPU, 5 with DAU Additional 6 with Junction Box	5 (Optional, 1 with QI-671P and 4 with QI-672P)	5 (Optional, 1 with QI-671P and 4 with QI-672P)	1 with QI-632P or 3 with QI-634P	N/A	2 (Optional with QI Equipped models)
Ventilators	Yes	Yes	Yes	Yes	N/A	Yes
CCO/SvO_2	Yes	Yes	Yes	Yes	N/A	Yes
Oridion MicroStream CO_2	Yes	Yes	Yes	Yes	N/A	Yes
SpO_2 for dual SpO_2	Yes	Yes	Yes	Yes	Yes, with JL-500 P1	Yes
Anesthesia Carts	Yes	Yes	Yes	Yes	N/A	Yes
$TcPO_2$ Units	Yes	Yes	Yes	Yes	N/A	Yes
Aspect BIS Monitor	Yes, External Interface or BISx Through Multiport Connector	Yes, External Interface or BISx Through Multiport Connector	Yes, External Interface or BISx Through Multiport Connector	Yes, External Interface or BISx Through Multiport Connector	N/A	Yes, External Interface or BISx Through Multiport Connector
Anesthetic Gas Module (AG-920RA)	Yes	Yes, Requires QF-904P Interface	Yes, Requires QF-904P Interface	Yes, Requires QF-904P Interface	N/A	Yes, Requires QF-904P Interface

	G9	TR6000	TR6000	TR6000	TPM	TR3000
	CSM-1901	BSM-6700	BSM-6500	BSM-6300	BSM-1700	BSM-3500
	Dimension and Weight					Dimension and Weight
Dimensions, in. (W,H,D)	Main Unit: 16 x 12.7 x 14.4 Display: 21.5	16.4 x 15.4 x 7.5	13.5 x 13.9 x 7.2	12.4 x 12.8 x 7.4	5.8 x 7.6 x 3.7	14.5 x 12.2 x 6.7
Weight, lbs	Main Unit: 27.5 Display: 12.1	22.7	18.3	11.7	3.5 (Including Battery)	13.6
List Price	From $31,800.00 to $34,000.00	From $17,490.00 to $26,600.00	From $15,250.00 to $23,200.00	From $8,220.00 to $12,660.00	From $7,560.00 to $7,830.00	From $3,900.00 to $6,262.00

EXHIBIT F

Bedside Monitor
BSM-3500

Quality Vital Sign Monitoring

- Compact, configured monitor with touchscreen display for ease of operation
- Ideal for ambulatory and specialty surgery centers
- Premium-as-standard design, providing all software options with base model
- Multiple Smart Cable™ ports for optimal parameter flexibility
- Comprehensive storage of multiple parameters to guide treatment decisions, including:
    - Arrhythmia detection and recall
    - ST analysis and recall
    - cap-ONE® Mainstream CO_2 sensor for intubated and non-intubated patients
    - Tabular and graphical trends
    - Full disclosure waveforms
    - Diagnostic 12-lead ECG

Specifications

Bedside Monitor BSM-3500

BSM-3500

DISPLAY

Display Size: 12.1" color TFT type LCD

Display Characteristics: Resolution: 800 x 600. Touch screen with six quick access hard keys

Maximum Number of Waveform Traces: Up to 14 traces

Display Waveforms: ECG (up to 12), respiration, IBP (up to 2), SpO_2 pulse wave, CO_2, BIS EEG (up to 2 traces), vent PAW, vent Flow, and CO Thermodilution curve. When gas is monitored: O_2 concentration curve, CO_2 concentration curve, anesthetic agent concentration (Halothane, Isoflurane, Enflurane, Sevoflurane, Desflurane) Analog input

Numerical Data Display: Heart rate, VPC rate, ST level, RR respiration rate, NIBP (systolic, diastolic, mean), IBP (systolic, diastolic, mean), SpO_2, SpO_2-2, delta SpO_2, pulse rate, temperature, CO, CI, Ti (injectate temperature), Tb (blood temperature), O_2 concentration, $EtCO_2$, BIS, inspired/ expired N_2O concentration, inspired/ expired CO_2, inspired/ expired O_2 concentration, inspired/ expired anesthetic agent concentration (Halothane, Isoflurane, Enflurane, Sevoflurane, Desflurane), MAC (minimum alveolar concentration), Ppeak (peak airway pressure), PEEP (positive end expiratory pressure), Pmean (mean airway pressure), MV (minute volume), TVi (inspiratory tidal volume), TVe (expiratory tidal volume), C (compliance), R (airway resistance), Ri (inspiratory airway resistance), Re (expiratory airway resistance), I:E (inspiration expiration ratio), SEF (90 or 95% spectral edge frequency), MDF (median frequency), PPF (peak power frequency), TP (total power), TP power of frequency, TOF, CCO, SVRI, SvO_2, EF, $ScvO_2$, CCI, EDV, SVR, EDVI, PCCO, PCCI, $tcPO_2$, $tcPCO_2$, PPV, SPV

ALARMS

Alarm Items: Vital sign alarms, arrhythmia alarms, technical alarms and operational alarms

Alarm Levels: Crisis (red blinking), Warning (yellow blinking), Advisory (yellow or blue light)

Alarm Indication: Alarm indicator (360° visibility) highlighted message, alarm sound

Alarm Suspend: 1, 2, or 3 min

PARAMETERS

ECG: Number of ECG waveforms channels: up to 12
Frequency response:
- Diagnosis mode: 0.05 to 150 Hz
- Monitor mode: 0.3 to 40 Hz
- Maximum filter mode: 1 to 18 Hz

Heart Rate Counting range: 0, 15 to 300 beats/min
Arrhythmia Analysis method: Multi-template software algorithm
VPC counting rate: 0 to 99 VPCs/min
Arrhythmia alarms: ASYSTOLE, VF, VT, V RHYTHM, V BRADY, EXT TACHY, EXT BRADY, AF, VPC RUN, COUPLET, EARLY VPC, BIGEMINY, TRIGEMINY, FREQ VPC, PROLONGED RR, SV TACHY, TACHYCARDIA, BRADYCARDIA, VPC, MULTIFORM, IRREGULAR RR, NO PACER PULSE, PACER NON-CAPTURE, PAUSE

ST Level Measurement: Number of measurement channels: up to 12
Measuring range: ±2.5 mV

Respiration (Impedance or Thermistor Method): Measuring range: 0 to 150 breaths/min

SpO_2: Measuring Technology: Nihon Kohden, Masimo or Nellcor
Measuring Display Range: 0 to 100% (70 to 100% at specified accuracy)
Pulse rate from SpO_2 Range: 0, 30 to 300 beats/min (varies by SpO_2 technology)

Non Invasive Blood Pressure, NIBP: Measuring method: Oscillometric Cuff
Pressure display range: 0 to 300 mmHg

Invasive Blood Pressure, IBP: Measuring range: –50 to 300 mmHg
Pulse rate display range from IBP range: 30 to 300 beats/min

Temperature: Measuring range: 0 to 45°C
Number of channels: 2 with Delta Temp

Cardiac Output: Measuring method: Thermodilution method
Measuring range: Injectate temperature (Ti): 0°C to 27°C
Blood temperature (Tb): 15°C to 45°C
Thermodilution curve (delta Tb): 0°C to 2.5°C
Cardiac output (CO): 0.5 to 20 L/min

Inspired Oxygen Fractional Concentration: Measuring range: 10 to 100%

CO_2: CO_2 measuring range: 0 to 150 mmHg
Respiration rate counting range: 0 to 150 breaths/min

BIS: Input channels: 2
Measuring parameters: Bispectral Index (BIS), 95% Spectral Edge Frequency (SEF90, SEF95), Suppression Ratio (SR), EMG, Signal Quality Index (SQI)

STORED PATIENT DATA

Trendgraph: Trend parameters: All monitored parameters
Trend display time: Up to 72 hours

Vital Signs List: All monitored parameters for up to 72 hours (1 per minute for 72 hours)

NIBP: Number of entries: 1,024 files

HEMO List: Number of entries: 1,024 files

Full Disclosure: Storage time: Up to 72 hours
Number of Waveforms stored: 5 maximum

ST Recall: Number of files: 4,320 files (1 per minute for 72 hours) for all monitoring leads

Alarm History: Number of entries: 16,384 files

Arrhythmia Recall: Number of files: 16,384 files

12-Lead Interpretive Recall: Number of files: 18 files

OCRG: Storage capacity: 72 hours

RECORDER (option)

Recording Method: Thermal array recording

Number of Channels: 3 traces (maximum)

POWER REQUIREMENT

AC: 100 to 240 V ±10%

Line Frequency: 50 or 60 Hz

Battery Operation Time (option): Up to 90 minutes

Power Consumption: AC 100 VA

DIMENSIONS AND WEIGHT

Dimensions: 370 W x 310 H x 172 D mm

Weight: 6.2kg

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EXHIBIT G

Rethinking Telemetry—and Its Impact on Healthcare

Wireless technology that improves care and reduces costs

NIHON KOHDEN

Thinking differently about telemetry.

You know it better than anyone—the challenge of improving quality while controlling costs is still with us—and telemetry is one area where this challenge has a dramatic impact both on patients and hospitals.

At Nihon Kohden, we're thinking differently about telemetry. Consider this:

What if you could monitor your at-risk patients throughout the facility and in the process improve care and reduce costs? And what if monitoring of your at-risk patients knew no bounds? With our family of multi-parameter telemetry products you could simultaneously watch over all patients, including those with cardiac conditions and co-morbidities, such as sleep apnea, obesity, and patients on opioid drips located in medical/surgical units.

Now you can.

Nihon Kohden offers the industry's most robust telemetry technology, bringing you immediate clinical and financial benefits.

Advanced telemetry for at-risk monitoring

It's vital that clinicians be able to quickly and accurately assess and document their patients' condition, in real time. The Nihon Kohden CNS-6201 is an advanced telemetry system with the following features:

Enhanced User Interface

Features direct-access keys to clinical information.

Fully Customizable

Clinicians can customize screens with a few simple keystrokes, enabling them to view the data they need, in the format they want.

Scalable

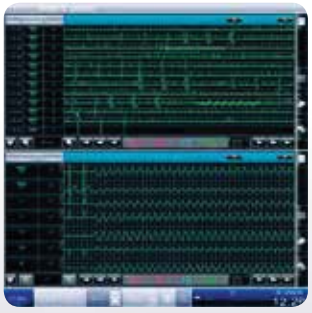
The system can accommodate up to 32 patients.

Better, faster assessment of patient information on a larger scale.

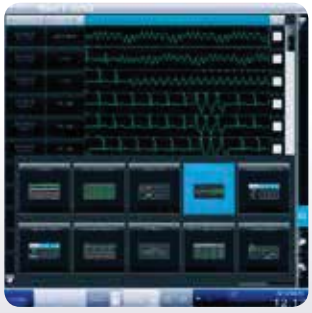
Clinicians can perform important assessment-related functions:

Individual patient review

Menu of review screens



Full-disclosure review

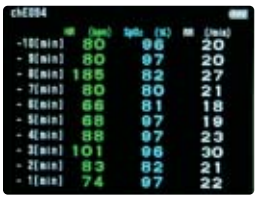


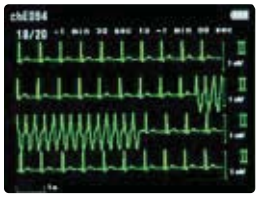
Customization of review screens

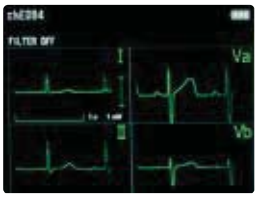
The industry's most robust line of transmitters

Nihon Kohden's telemetry transmitters are ideal for patients that require ambulatory monitoring, from the traditional cardiac telemetry units to the medical/surgical floors. We have the right transmitter for the entire patient population regardless of acuity level or location.

Vital signs


Tabular trends


Full disclosure



Multi-lead

Monitors and displays:

NTX/ZM-540/541PA

Monitors ECG (3 or 6 lead), respiration, continuous SpO_2, and NIBP

Battery life: 24 hours with NIBP at 1 hour intervals

ZM-530/531PA

Monitors ECG (3 or 6 lead), respiration, and continuous SpO_2

Battery life: 60 hours

ZM-520/521PA

Monitors ECG (3 or 6 lead) and respiration

Battery life: 72 hours

The benefits of Defensive Monitoring

It's clear that earlier detection of patient distress results in faster intervention and higher patient safety. Yet, continuous patient monitoring typically takes place only in areas where patients are deemed most at risk, such as ICU and cardiac telemetry. Defensive Monitoring provides continuous vital sign surveillance to the traditionally un-monitored, at-risk patient located in the medical/surgical units.

A new algorithm for patient monitoring

The Nihon Kohden Defensive Monitoring strategy includes the Prefense® Early Detection and Notification System.™ Our fifth-generation Prefense system features an FDA-cleared smoothing algorithm, providing a more accurate representation of a patient's condition. With Prefense, surveillance is both constant and efficient. Caregivers immediately get the vital information they need to determine the status of their patient—resulting in faster interventions when required, while reducing false alarms by more than 75 percent.

The advantages are significant:

- Enhanced and reliable point of care surveillance
- Decrease unplanned and costly ICU and cardiac telemetry admissions
- Better bed utilization while reducing length of stay

Monitored Parameters:

Heart Rate, Pulse Oximetry, Respiration, Non-Invasive Blood Pressure, $EtCO_2$

Prefense can immediately help hospitals meet their dual challenge of increasing quality while cutting costs.

Different thinking to address today's challenges

Faced with the challenge of improving care quality—while controlling costs—healthcare providers seek business partners who enable real change. Who think differently.

At the forefront of change within the healthcare continuum, Nihon Kohden is uniquely suited to empower providers to meet these challenges and surpass patient quality and safety initiatives. Nihon Kohden provides quality, reliable technology, and drives integration at the clinical level, across all care areas. As a result, with Nihon Kohden technology, clinicians can access a higher level of information, enabling more accurate diagnoses and ultimately, better outcomes.

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MMLB 058(B)-CO-1174

EXHIBIT H

Central Monitoring System
CNS-6201A

Patient Monitoring and Review Capabilities

- Delivering information throughout the continuum of care
- Scalable solution to meet any monitoring requirement
- Monitors up to 32 patients using two displays
- Combines hardwired, wireless and telemetry monitoring into a single solution
- Comprehensive data storage and review
- Automated patient and data transfer between multiple departments insuring a comprehensive patient record
- Export data to Hospital Information System using CGS-9002 HL7 Gateway System

Specifications

Central Monitoring System
CNS-6201A

CNS-6201A

DISPLAY

Size/Type: 24" color LCD display with touch screen operation

Resolution: 1920 × 1200

Number of Patients: Up to 32 with two displays. 4, 6, 8, 10, 12 or 16 patients per display, selectable

Waveform Display Items (depends on the connected monitor/transmitter): ECG (up to 12 vectors), IBP (1-8), respiration wave, pulse (SpO_2), EEG (1- 2), Flow/Paw, CO_2, external input, Anesthetic gas (O_2, CO_2, N_2O, Agent)

Number of Traces, All Beds Screen: Up to 24 total per display, number per patient is based on number of patients displayed.

16 patients – 2 traces each, 12 patients – 3 traces each, 10 patients – 4 traces each, 8 patients – 5 traces each, 6 patients – 8 traces each, 4 patients – 12 traces each, 2 patients – 16 traces each

Number of Traces, Individual Bed Screen: Up to 16

Waveform Sweep Speed: 25 mm/s, 50 mm/s, 6.25 mm/s (respiration measurement)

Alphanumeric Display Items (depends on the connected monitor/transmitter): Heart rate, Pulse rate, VPC rate, respiration rate, ST level, IBP (systolic, diastolic, mean), SpO_2, CO_2, Cardiac Output, blood temperature, CCO, CCO<Tb>, CCI, NIBP (systolic, diastolic, mean), temperature, SvO_2, PiCCO, Flow/Paw, N_2O, O_2, Agent, BIS, $tcPO_2$, $tcPCO_2$, TV, MV, PEEP, others.

ALARMS

Alarm Type: Crisis, Warning, Advisory, Technical

Alarm Items (depends on the connected monitor/transmitter): Vital signs: Heart rate, Pulse rate, Respiration rate, Apnea, ST level, IBP (systolic, diastolic, and mean), NIBP (systolic, diastolic, and mean), Temperature, Delta T, Tb, SpO2, SvO2, CCO, ventilator, anesthetic gas, BIS, EtCO2, FiCO2, EtO2, FiO2, N2O, O2, tcPO2, tcPCO2, MV, Ppeak, PEEP

Arrhythmia: Asystole, V.Fib, Ext. Tachycardia, Ext. Bradycardia, V. Tachy, Tachycardia, Bradycardia, VPC Run, Couplet, Early VPC, Multiform, Bigeminy, Freq. VPC, Prolonged

Alarm Display: Alarm indicator with flashing bed frame and highlighted numerical display and highlighted alarm message

Alarm Recording: Automatic

Alarm Icon/ Arrhythmia Icon: Available when vital sign, technical alarm, or arrhythmia occurs

DATA STORAGE

Graphical Trend: 120 hours, all parameters

Tabular Trends: 120 hours, all parameters, minute-by-minute

Arrhythmia Recall: 1,500 events per bed with 8 second strip.

Full Disclosure: 120 hours, 16 traces per bed

ST Level: 120 hours, minute-by-minute

Hemodynamic List: 256 files per bed

12-lead ECG Analysis Files: 200 files per bed

Event History: 10,000 events per bed, includes arrhythmia events, limit alarms, technical alarms, system alarms, caliper measurements and comments

OVERVIEW

Displays user-selectable vital signs, up to 12 ECG waveforms, reviews, alarm events, and status messages associated with the selected overview bed. The overview bed can be any bed in the network that the CNS is not monitoring.

THERMAL ARRAY RECORDER, WS-960P

Recording Method: Thermal array recording

Number of Waveforms: 3

Paper Speed: 25 mm/sec

Type of Recording: Manual, alarm, periodic, remote

NETWORK LASER PRINTER

HP LaserJet M602DN or equivalent (Postscript printer)

Number of Waveforms: Up to 16

Type of Recording: Manual, periodic

USER INTERFACE

Touch screen, mouse, keyboard and wireless remote controller

POWER REQUIREMENTS

Line/Battery Voltage: AC 100 to 240 V, 50 or 60 Hz

Power Consumption: 180 VA or less

ENVIRONMENT

Operating Temperature: 10° to 35°C

Storage Temperature: –20° to 60°C
VL-931R (–10° to 60°C)

Operating Humidity: 30 to 80 % RH

Storage Humidity: 20 to 90 % RH

Operating Atmospheric Pressure: 70 to 106 kPa

Storage Atmospheric Pressure: 70 to 106 kPa

DIMENSIONS AND WEIGHT

PU-971R Main Unit: 4.5" W × 13.8" H × 15.0" D, 24.2 lbs

E282678 LCD Unit: 23.4" W × 15.7" H × 8.4" D, 24.2 lbs

WS-960P Recorder: 3.2" W × 2.9" H × 6.7" D, 1.6 lbs

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EXHIBIT I

Remote Network Station
RNS-9703

Secondary Patient Monitoring and Review Capabilities

- Effectively access and review clinically relevant patient data from multiple locations with diverse hardwired and telemetry monitoring environments
- Intuitive, real-time management of monitored data from locations other than the traditional central station
- Ability to arrange the 16 patient display by care area, acuity level and monitoring type
- Focuses staff attention on key information that can help speed interpretation and improve outcomes
- Enhancing access to care, safety, clinician workflow and patient satisfaction

Specifications

Remote Network Station
RNS-9703

RNS-9703-19 and RNS-9703-24

DISPLAY

Size/Type: 19" or 24" color LCD display

Resolution: 1920 × 1200

Number of Patients: 4, 6, 8, 10, 12 or 16 patients per display

Waveform Display Items (depends on the connected monitor/transmitter): ECG (up to 12 vectors), IBP (1-8), respiration wave, pulse (SpO_2), EEG (1- 2), Flow/Paw, CO_2, external input, Anesthetic gas (O_2, CO_2, N_2O, Agent)

Number of Traces, All Beds Screen: Up to 24 total per display, number per patient is based on number of patients displayed.

16 patients – 1 trace each, 12 patients – 2 traces each, 10 patients – 2 traces each, 8 patients – 3 traces each, 6 patients – 4 traces each, 4 patients – 6 traces each

Number of Traces, Individual Bed Screen: Up to 16

Waveform Sweep Speed: 25 mm/s, 50 mm/s, 6.25 mm/s (respiration measurement)

Alphanumeric Display Items (depends on the connected monitor/transmitter): Heart rate, Pulse rate, VPC rate, respiration rate, ST level, IBP (systolic, diastolic, mean), SpO_2, CO_2, Cardiac Output, blood temperature, CCO, CCO<Tb>, CCI, NIBP (systolic, diastolic, mean), temperature, SvO_2, PiCCO, Flow/Paw, N_2O, O_2, Agent, BIS, $tcPO_2$, $tcPCO_2$, TV, MV, PEEP, others.

ALARMS

Alarm Type: Crisis, Warning, Advisory, Technical

Alarm Items (depends on the connected monitor/transmitter): Vital signs: Heart rate, Pulse rate, Respiration rate, Apnea, ST level, IBP (systolic, diastolic, and mean), NIBP (systolic, diastolic, and mean), Temperature, Delta T, Tb, SpO_2, SvO_2, CCO, ventilator, anesthetic gas, BIS, $EtCO_2$, $FiCO_2$, EtO_2, FiO_2, N_2O, O_2, $tcPO_2$, $tcPCO_2$, MV, Ppeak, PEEP

Arrhythmia: Asystole, V.Fib, Ext. Tachycardia, Ext. Bradycardia, V. Tachy, Tachycardia, Bradycardia, VPC Run, Couplet, Early VPC, Multiform, Bigeminy, Freq. VPC, Prolonged

Alarm Display: Alarm indicator with flashing bed frame and highlighted numerical display and highlighted alarm message

Alarm Recording: Automatic (option)

Alarm Icon/ Arrhythmia Icon: Available when vital sign, technical alarm, or arrhythmia occurs

OVERVIEW FUNCTION

Displays user-selectable vital signs, up to 12 ECG waveforms, reviews, alarm events, and status messages associated with the selected overview bed. The overview bed can be any bed in the network that the RNS is not monitoring.

THERMAL ARRAY RECORDER, WS-960P (OPTION)

Recording Method: Thermal array recording

Number of Waveforms: 3

Paper Speed: 25 mm/sec

Type of Recording: Manual, alarm, periodic, remote

NETWORK LASER PRINTER (OPTION)

HP LaserJet M602DN or equivalent (Postscript printer)

Number of Waveforms: Up to 16

Type of Recording: Manual, periodic

USER INTERFACE

Mouse and keyboard

RNS-9703 19" THIN CLIENT COMPUTER

Dimensions: 407 x 452.9 x 210 mm / 16 x 17.8 x 8.2 inches

Weight: 5 Kg / 11 lbs.

Power Consumption: 100-240V, 50/60Hz, 0.5A

Operating Temperature: 50°F ~ 104°F (10°C ~ 40°C)

Operating Humidity: 10 % ~ 80 %, non-condensing

Storage Temperature: -4°F ~ 113°F (-20°C ~ 45°C)

Storage Humidity: 5 % ~ 95 %, non-condensing RNS-9703-019

RNS-9703 24" THIN CLIENT COMPUTER

Dimensions: 554.6 x 510.3 x 224 mm / 21.8 x 20 x 8.8 inches

Weight: 6.1 Kg / 13.4 lbs.

Power Consumption: 100-240V, 50/60Hz, 0.5A

Operating Temperature: 50°F ~ 104°F (10°C ~ 40°C)

Operating Humidity: 10 % ~ 80 %, non-condensing

Storage Temperature: -4°F ~ 113°F (-20°C ~ 45°C)

Storage Humidity: 5 % ~ 95 %, non-condensing RNS-9703-024

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EXHIBIT J

Life Scope G9 Bedside Monitor

A new standard in monitored care

NIHON KOHDEN

Adaptive Care – Quality Outcomes

Outcomes and quality have taken center stage for healthcare systems today. Full featured, acuity-adaptable monitoring allows care providers to affect patient-centered care across critical care settings while creating common metrics and shared protocols that improve outcomes.

Nihon Kohden's Life Scope G9 is a fully optimized bedside monitor that allows high acuity care teams to be uniquely patient ready, ensuring a level of patient monitoring that is without compromise.

With drag-and-drop customizable caregiver-specific display options, the G9 can be personalized to each patient and caregiver regardless of the patient's health status or setting within the hospital—giving care teams the confidence that they have the right monitoring solution for each patient, every time.

Maintaining a high standard of monitoring care, even during transport, is ensured with the G9 and Life Scope Transport monitor. Using the Life Scope Transport monitor as an input box, your patient is transferred with all G9 monitored parameters that are uploaded to the new care area bedside display, creating one seamless patient record for enhanced workflow and care coordination.


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Tailored Care for You and Y

Nihon Kohden's inclusive monitoring philosophy continues with the Life Scope G9. This full-featured system provides comprehensive parameter monitoring with data storage, including multi-waveform/multi-parameter full disclosure, comprehensive arrhythmia and ST segment analysis, as well as 12-lead ECG capability, and drug, hemodynamic and pulmonary calculations that ensure a high standard of monitoring care across patient conditions.

our Patient

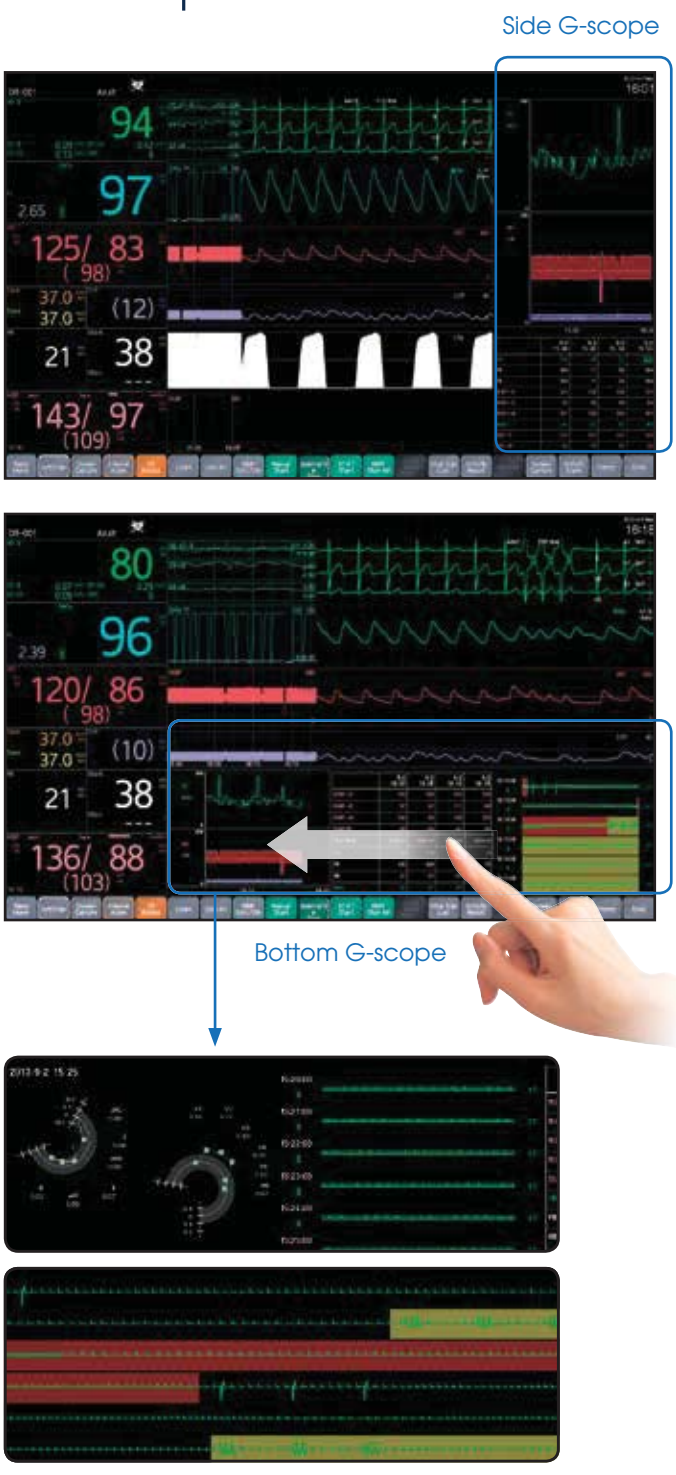
Nihon Kohden's unique Smart Cable™ technology miniaturizes circuits found in traditional modules and embeds that circuitry into a smart patient cable. When you plug a Smart Cable into a MultiPort, the associated parameter is automatically detected, displayed and measured. With this technology, you'll get parameter flexibility at a significantly reduced cost with seamless and immediate access to blood pressure, cardiac output, $EtCO_2$, temperature, BIS and more, when and where you need it for rapid clinical assessment from the ER to the ICU.

Life Scope G9 offers care area-specific functionality to optimize specialty monitoring. For example, up to three independent monitoring screens allow unique display configurations for multi-clinician oversight in the Operating Room.

Decision Support at Your Fingertips

Designed with quick clinical access in mind, one or two clicks allow you to view the most important information associated with any monitored parameter for quicker assessment and intervention, depending on your patient's condition.

Review previous data while retaining full view monitoring of all vital signs and waveforms using our exclusive G-scope. Simply flick the side or bottom of the screen and select from three user-defined review screens for decision support and cross care area collaboration after transport.



Seamless Transport

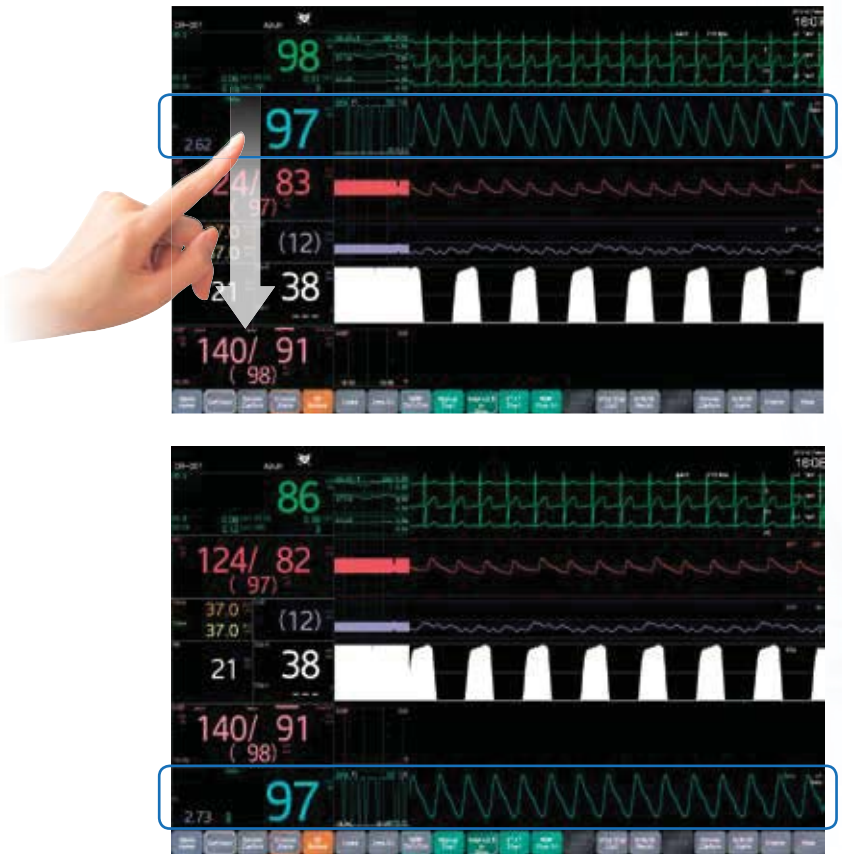
With today's high acuity patients, it is important to maintain a high standard of monitoring care, even during transport. The unique design of Nihon Kohden's BSM-1700 Transport monitor and the Lifescope G9 Data Acquisition Unit redefines transport monitoring. Simply disconnect the BSM-1700 Transport monitor from the Data Acquisition Unit and your patient can be transported with all monitoring capabilities remaining the same. When the patient is transferred to their new care setting and the BSM-1700 is reconnected to another G9 or BSM-6000 monitor, patient information, including full disclosure, is uploaded to the new bedside display creating one seamless patient record enhancing workflow and care coordination.

Enhanced Patient Experience

Patient-centered care can improve patient outcomes and satisfaction. With Life Scope G9's Sleep Mode, the bedside monitor is darkened and the ECG synch sound and alarm indicator are disabled, preventing the monitor from disturbing the patient during rest or sleep. When the Life Scope G9 is connected to the Central Monitor, both the patient and clinical staff can rest assured that full monitoring capabilities remain.

Further oversight is ensured with interbed monitoring of vital information and alarm status of another bed in the network.

The integrated 12-Lead ECG capability of the Life Scope G9 offers the same reliability of a dedicated ECG machine, minimizing the need to change patient electrodes and burden the patient with additional stand-alone ECG testing.



Screen layouts can be tailored by clinician preference or individual patient care needs using G9's drag and drop screen builder and setup configuration. Customizable screen layouts can be saved by user profile for quick recall and application to personalize patient care.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Quality of Care

The acuity-adaptable Life Scope G9 monitoring system from Nihon Kohden allows one standard of care across the acuity care continuum, thereby leveraging collaboration and care coordination that can improve quality and outcomes. In today's healthcare environment, quality of care is the common denominator to employee and patient satisfaction. Let us help you make your outcomes more predictable.

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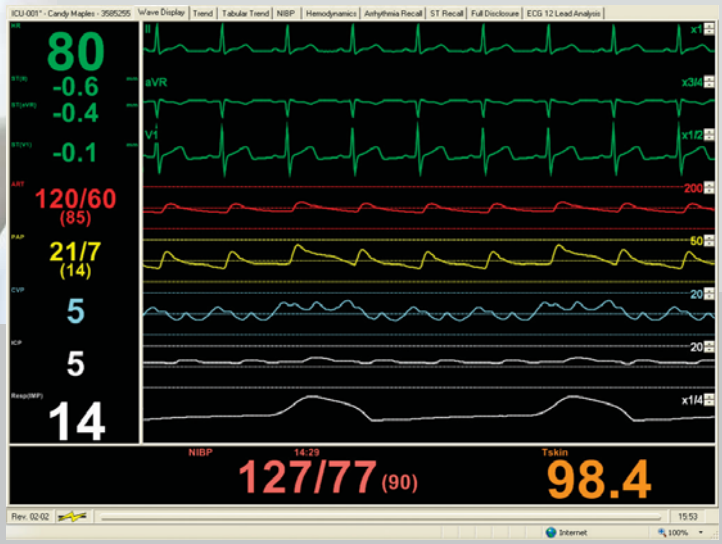
Different Thinking for Better Healthcare.®

MMLB 038(D)-CO-1236

EXHIBIT K

Remote Access System
QP-983P NetKonnect



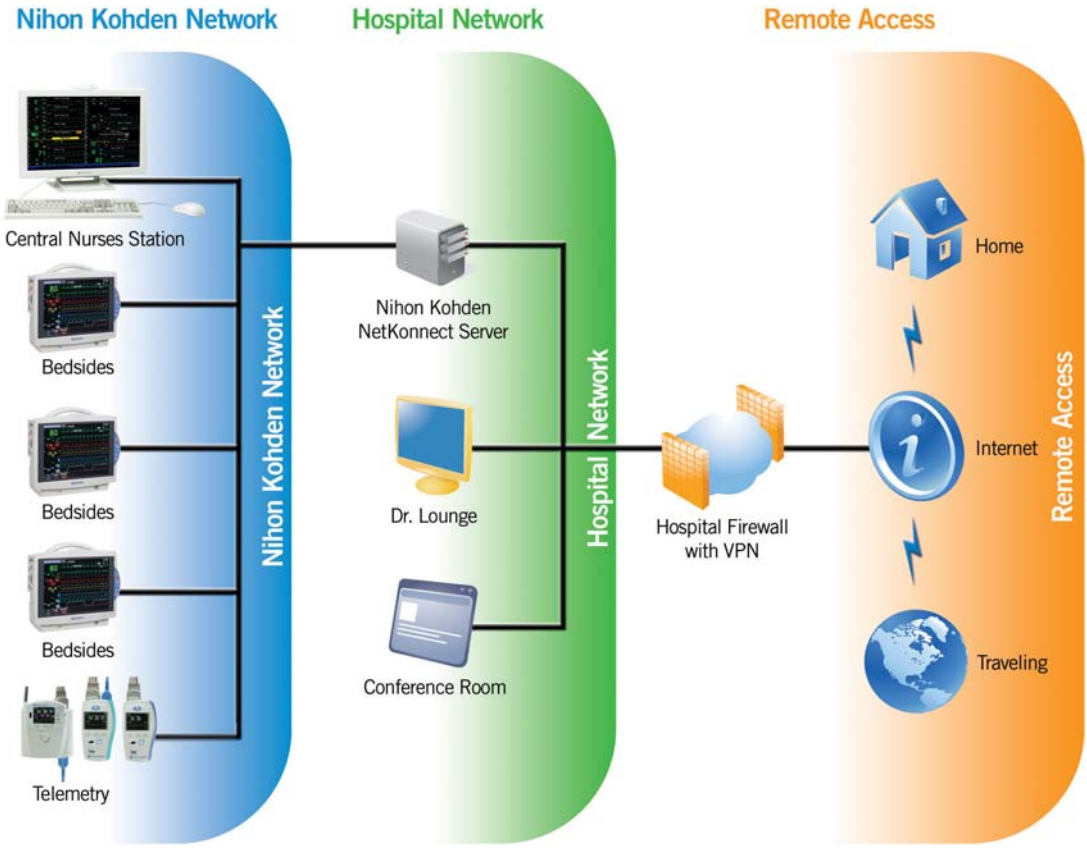
Comprehensive Web-based Application Provides a Portal to Your Monitored Patients

- HIPPA compliant secured access for local or remote users
- Individual nurse review stations
- Remote physician and nurse access
- Near real-time waveform and numerics with user selectable settings for customized views
- Interactive and time-linked monitoring data:
    - Graphical and Tabular Trends
    - Hemodynamic Calculations
    - Arrhythmia Recall Events
    - Minute-to-minute ST Templates
    - Multi-Parameter Full Disclosure Waveforms
    - Interpretative 12-lead ECGs

Remote Access System
QP-983P NetKonnect

NetKonnect provides you with the information to make clinical decisions when timing is critical.

The QP-983P NetKonnect Remote Access Server provides a secure portal between the Nihon Kohden patient monitoring system and your hospital's network. You can use most web-enabled computers* to access this data both locally and remotely. Once you access the hospital's network, simply click on the NetKonnect desktop icon to log on with your user name and password. Only authorized users are allowed to access this data.



Convenient access to patient data leads to improved patient outcomes.

- Clinicians have access to their patients' current and stored monitoring data from within the hospital, from their offices or from their homes.
- NetKonnect provides immediate access to patient data so that physicians can complete their clinical assessment before ordering interventions. This results in improved decision-making, improved patient outcomes and physician satisfaction.
- NetKonnect makes the charting function more efficient by allowing clinicians to view physiologic data in conjunction with the electronic chart instead of requiring them to go to a central location for this purpose.
- HIPPA compliant secured access insures that only authorized personnel have access to patient data.

*Requires Internet Explorer 5.1 or later and .Net Framework 1.1 or later

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